EXHIBIT H

CAUSE NO. 2013-DCL-3511-D

SANDRA GARCIA, Plaintiff, vs. RODOLFO J. WALSS, M.D., RODOLFO J. WALSS, M.D., P.A., JOHNSON & JOHNSON, INC. and ETHICON, INC., Defendants.	)	IN THE DISTRICT COURT 103rd JUDICIAL DISTRICT CAMERON COUNTY, TEXAS

DEPOSITION OF

SUZANNE PARISIAN, M.D.

Phoenix, Arizona
February 12, 2015
9:04 a.m.

LEO T. MANKIEWICZ, CR, RMR, CRR
Arizona Certified Reporter
Certificate No. 50778

BE IT REMEMBERED THAT THE DEPOSITION OF SUZANNE PARISIAN, M.D.

was taken on behalf of Defendants, at the Hilton Phoenix Suites, 10 East Thomas Road, Phoenix, Arizona, commencing at 9:04 a.m., on Thursday, February 12, 2015, before Leo T. Mankiewicz, Arizona Certified Reporter, Certificate No. 50778, pursuant to Notice of Deposition.

APPEARANCES:

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(by telephone conference)

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Thursday, February 12, 2015

9:04 a.m.

P R O C E E D I N G S

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SUZANNE PARISIAN, M.D.,

CALLED AS A WITNESS, HAVING BEEN DULY SWORN, TESTIFIED AS FOLLOWS:

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EXAMINATION BY MR. HUTCHINSON

BY MR. HUTCHINSON:

Q Good morning, Dr. Parisian. How are you doing?

A Fine.

Q My name is Chad Hutchinson. I represent Johnson & Johnson and Ethicon in this case. I'm here to take your deposition, do you understand that?

A Yes, sir.

Q You've been deposed before, correct?

A Yes, sir.

Q You understand you're subject to the penalty of perjury?

A Yes, sir.

Q If you don't understand one of my questions, will you let me know?

A Yes, sir.

Q Otherwise, I'm going to assume you understood my question. Is that fair?

A Yes, sir.

Q You've been offered as the plaintiff's expert in the Garcia case, is that right?

A Yes, sir.

Q In what field?

A For FDA regulatory issues.

Q Is that your specialty?

A Yes, sir.

Q Any other specialties?

A Well, I have other specialties, but that's where I see my role, as an FDA regulatory expert.

Q In this case?

A Yes, sir.

Q Okay, any other roles in this case?

A No, sir.

Q Have you ever been retained as an expert witness in a mesh case before this one?

A Yes.

Q And which one?

A I believe I was involved with the C.R. Bard Marlex mesh. I was involved with other surgi- -- AMS

mesh, I've been involved with Boston Scientific's transvaginal mesh. Those are the ones I recall. Oh, no, Kugel, Kugel mesh.

Q And you testified against the manufacturer in all those cases?

A Yes, sir.

Q Are you still working in an expert capacity for any of those manufacturers?

A You mean for those cases? Yes, sir.

Q Approximately how many cases?

A Right now, this is the only mesh case I have.

Q Against Ethicon?

A No, against anybody. I don't have any active -- I'm still involved, but I don't have any active cases that I'm aware of.

Q Okay. Well, in how many cases have you been providing expert testimony against manufacturers of mesh products?

A Well, those would be the issues.

Q How many cases are we talking about?

A I don't know, because they're MDLs. I was the expert for the AMS MDL. I don't know how many cases were in that before it settled, and then it was like, I think I gave a deposition for one case that wasn't in

the MDL, or -- no, two, two. So I don't know how big the MDLs are. I've just been hired for litigation.

Q Okay, but you would be an expert for each and every plaintiff in that -- in the MDLs, correct?

A Yes, sir, if they needed me for the case, yes, sir. So I don't know how big those MDLs are; unlike this case, which is here, I know it's a single plaintiff.

Q For -- let's talk about Ethicon in particular, okay?

A Yes, sir.

Q How many mesh cases have you been involved in against Ethicon?

A Only this one.

Q And if my math is correct, since 1997, you've testified in court 81 times for a plaintiff, is that right?

A Yes, sir. Those are the -- those aren't all the cases I've had, but those are the ones that have gone to court.

Q And you've always testified for the plaintiff in pharmaceutical and medical device cases?

A In court, yes, but I have been an expert witness for a medical device manufacturer. I think it

was Clinical Innovations, so I was their expert.

Q And how long ago was that?

A That was several years ago.

Q Over 20?

A No, no, no, not over 20. It was actually, I think it was actually, like, six years ago. It went off my five-year list, but -- and then when I first started out, if you want my full -- I was also the expert for pedicle screws for industry. So I've testified for industry, I've testified for hospitals, I've testified for industry versus industry. So not every case is a case like this case.

Q You've never testified for a defendant in court, have you?

A Yes, I have, in court, yes, sir, but I believe it was a hospital, Wash- -- hospital, Seattle Children's Hospital. There wouldn't be any reason I wouldn't, if I accepted a case.

Q Have you ever turned down a pharmaceutical medical device case for a plaintiff?

A Oh, yes. I don't take every case given to me.

Q I'm handing you what I've marked as Exhibit 1 to your deposition. Do you have that in front of you?

A Yes, sir.

(Whereupon, Exhibit 1 was marked for identification.)

BY MR. HUTCHINSON:

Q And if you'll look on the last page, we had asked for some documents. Do you see those?

A Yes, sir.

Q Did you bring those documents with you today?

A I didn't bring my curriculum vitae, but I thought you had received that. I've tried to bring everything else that I have, and then I think I helped generate a list of documents I've relied on.

Q Okay, and just so the record is clear, you've brought everything that you have that is responsive to the document request 1 through 9, correct?

A Yes, sir. I have brought what we call my file.

Q And you have your file in front of you, is that correct?

A Yes, sir.

Q Why don't we do this. And just for the record, your file consists of two black binders, one of which is called "TVT Secur" on the front, and the other one is called, "Documents-TVT Secur," right?

A Yes, sir.

Q And each document has a bunch of tabs, and a lot of documents that you've reviewed for this case?
A Yes, sir, and it's all my handwriting and my tabs.
Q And then we have a separate stack of loose paper in front of you that you've brought responsive, correct?
A Yes, sir.
Q And what does this stack represent?
A Okay. It would be the rest of my file, and it represents my designation as an expert witness, what we're going to talk about today, the amended report of John Miklos, a list of documents that I've relied on, the deposition notice, my billing records, all the records that I've generated as well as the ones getting ready for the deposition today that hasn't been billed; some agreement for the protective order; the Has French National Authority for Health report, November 2006; some other articles that I've found, we'll put it that way. Those are articles I've found.
So the medical literature that I have here, the searches are from my -- I've obtained those, and the advertising from Johnson & Johnson for the Ethisorb product; my communication that came with my binder; the

510(k) for AMS products, which was one of the -- another product, as well as the 510(k) -- I'll give -- K021263, which was for the SPARC Sling System; the Codman Ethisorb Dura Patch 510(k), K991413; the 510(k) clearance for the Gynecare TVT Secur device, and that's K052401.
I had done a search at one time of the suture materials that are used for the mesh, the PDS absorbable product, and I believe Vicryl. So I brought those 510(k)'s that are stapled together.
And then, let's see, I brought the patents -- trademark for the Monitorr, M-O-N-I-T-O-R-R device; and then last night, I brought -- I went and did a really quick look at the Medical Device Reports for Gynecare TVT, and I've brought those documents, kind of summarized together.
Q Okay, and that was for Gynecare TVT and not TVT Secur, right?
A No, it was the -- only way to get Secur is if you use TVT Gynecare and then Secur. So I did do it looking at Secur, but it had to come up under TVT Gynecare.
Q Okay, and in this one stack of loose documents, and the two black notebooks, they have some

handwriting and highlights in them, correct?
A Yes, sir.
Q And all the handwriting and highlights were done by you, correct?
A Yes, sir.
Q And nobody else.
A Yes, sir.
Q And why don't we go on and mark --
A Except for the ones that are printed with a highlighting. If they're yellow, they're mine.
Q And let's go ahead and mark as Exhibit -- as a collective Exhibit 2 your two black notebooks and the loose paper, as Exhibit 2, okay?
A Um-hum.
MR. LUNDQUIST: Well, obviously, when we -- I mean, we can receive copies.
MR. HUTCHINSON: We'll have copies of them.
MR. LUNDQUIST: Okay, all right.
(Whereupon, Exhibit 2 was marked for identification.)
BY MR. HUTCHINSON:
Q And does Exhibit 2 reflect every sheet of paper that you used to formulate your opinion in this case?

A No, no, because I mean, I've had a history of mesh products before. So you couldn't bring every document that -- because I've dealt with mesh and the same with the other vaginal mesh products, and I mean, my knowledge of these types of products go back to ProtoGen, which is a long time ago. So it's not -- but the ones that I have specifically used for Ethicon are here.
Q Okay. Well, that was my question, thank you. So Exhibit 2 would represent all of the materials that you relied on in this particular case to reach opinions, correct?
A With the caveat that there's a background that I have. I can't bring that. That's been acquired over years.
Q I understand. All right, thank you. Let's look at your CV. We'll mark it as Exhibit 3. I recognize it's in here, but I've got a clean copy.
A Thank you.
(Whereupon, Exhibit 3 was marked for identification.)
BY MR. HUTCHINSON:
Q This is the most current copy of your CV?
A Yes. I believe -- I think so. I'm not sure.

There's nothing really significantly different. I just might have had a different date on it, but I haven't done anything different.

Q All publications are included on your CV?

A Yes, sir.

Q You've never published anything in a peer-reviewed journal, have you?

A Well, no. I have in terms of when I was in developmental biology.

Q Have you ever published anything on a cervical mesh?

A No.

Q Proline?

A No.

Q TVT Secur?

A No.

Q Anything on SUI?

A No, sir.

Q You understand SUI means stress urinary incontinence?

A Yes, and I began looking at SUI issues when I was at the FDA.

Q You've never published on dyspareunia or pelvic pain?

A No.

Q Let's talk about presentations. Are all the presentations that you've given included within your CV?

A Yes, sir.

Q Have you ever presented on surgical mesh?

A No, sir.

Q Proline?

A No, sir.

Q TVT Secur?

A No, sir.

Q SUI?

A No, sir.

Q Dyspareunia or pelvic pain?

A No, sir.

Q Your research experience, is all that included within your CV marked as Exhibit 3?

A Yes, sir. I haven't done any hands-on testing. I think that's what you're asking, about mesh. No.

Q No hands-on testing for any type of surgical mesh?

A That is correct.

Q And no hands-on testing for any type of product to treat stress urinary incontinence?

A I've actually consulted for firms for devices for stress urinary incontinence that are radiofrequency devices for treating that.

Q We'll get to that in a minute, but let's stay on hands-on testing.

A I haven't done any hands-on testing, I just consulted.

Q For any type of SUI device?

A Yes, sir. No, I did. I did do that.

Q Oh, you did do that.

A Yeah, I did do consulting for an SUI device, but I didn't do hands-on testing. I did regulatory consulting.

Q All right. Just so the record's clear, you've never done any hands-on testing for any type of stress urinary device, correct?

A Correct.

Q Let's talk about your correspondence with Ms. Garcia's counsel. When were you first contacted in this case?

A I don't -- I think around sometime in the summer, in July-ish. I was looking at buying a house, and he caught me, and I was in the middle of talking to realtors and stuff.

Q He called you on your cell phone?

A Yeah, and I didn't buy the house, so I remembered that --

Q That was in the summer of 2014?

A Yes, sir.

Q And what were you asked to do in this case?

A I was asked if I would accept looking at the case. I mean, I was familiar with vaginal mesh from AMS and I had had to look at issues with Ethicon before, so he asked if I would look at an Ethicon issue.

Q Okay, and what did you tell him you'd do?

A I told him -- what did I tell him I'd do? I told him I would look at it and I'd give him opinions as to whether I would want to take the case.

Q Have you ever spoken -- and who was that that called you, Mr. Lundquist?

A Mr. Lundquist. He has my number.

Q Had you ever spoken with Mr. Lundquist before that first time?

A Yes, I had worked with them on, I believe -- AMS? Yes, AMS, for the MDL.

Q Had you worked with Mr. Lundquist and his firm for any other MDLs?

A Paxil, I was involved with Paxil, and I'm not

sure who all the people are in MDLs. I know was with Trasylol, I was involved.

Q Trasylol?

A Trasylol; and Paxil, and I'm not sure what other ones I've been involved with.

Q Okay.

A Those are the ones I directly spoke to members of his firm.

Q That's at least four MDLs that you've been working with Mr. Lundquist's firm on, correct?

MR. LUNDQUIST: Objection, form.

THE WITNESS: Well, I'm not working on an MDL, I'm just working on this particular case. So that would be that they were part of an MDL group, as you know, which could be hundreds of attorneys, for Paxil and -- so it was really -- was it four? Yeah, but this isn't an MDL, as far as I know.

BY MR. HUTCHINSON:

Q Right. When did you first start working with Mr. Lundquist's firm?

A Mr. Lundquist -- the firm? The firm, the first time I met -- that I remember meeting somebody from that firm was for Paxil, which would have been years ago.

Q How many years ago?

A I'm not sure when that was. I'm not sure -- I met them at the Kilker trial was the first time I met someone from his firm, and I don't know when that was. That was the only Paxil trial in Philadelphia.

Q Would that have been more than 10 years ago?

A I don't think it was that long ago. It was less than that. It was probably, I don't know, eight years ago, four years ago?

Q Have you met with Mr. Lundquist before today's deposition?

A Yes, sir.

Q How many times have you met?

A For this deposition, I met with him once. I met with him for three and a half hours, and that's where we put together what my opinions would be for the disclosure.

Q Okay.

A The only error he has is that I get $600 an hour for court testimony and deposition. He has it only as 400. That's an important one to me.

Q So you've reviewed that expert disclosure pretty thoroughly, correct?

A Yes, sir.

Q Okay, and did you meet with Mr. -- when did you have that meeting with Mr. Lundquist to review the expert disclosure?

A I believe it was in August. It's on my billing records. I can look at my bills.

Q And is that the only time you've met with Mr. Lundquist?

A Yes, sir. Well, yesterday, I met with Mr. Lundquist yesterday to discuss what I was going to bring.

Q And how long did you meet with Mr. Lundquist yesterday?

A We met for about four hours.

Q So the meeting in August that was three and a half hours, and your meeting yesterday that was four and a half hours, would be the sum total of the two meetings with Mr. Lundquist, correct?

A Yes, sir.

Q Has anybody met -- has anybody participated in those meetings with you and Mr. Lundquist?

A No.

Q It's just been you and him on it only?

A Yes, sir.

Q Other than with Mr. Lundquist, have you

discussed this case with anybody?

A No, sir, nor would I think I would be permitted to do that. And by that I mean, by the protective order.

MR. HUTCHINSON: All right, so let's look at what we'll mark as Exhibit number 4.

(Whereupon, Exhibit 4 was marked for identification.)

BY MR. HUTCHINSON:

Q So Mr. Lundquist made an error on the amount per hour on Exhibit 4, and that should be $600 per hour rather than 400, basically, is what you're saying? Is that correct?

A For court and deposition testimony. It's $400 an hour for work, that's correct, but it's for the other would be what you're paying today, I guess, is $600 an hour.

Q Okay, well, let me make sure I understand. It's $400 for your review of documents and records, correct?

A Yes, sir, when I stay in my office and just am working on my case.

Q And it's $600 per hour when you're giving testimony at trial or in a deposition, correct?

A Yes, sir.
Q Do you still have a standing $6,000 per day amount for trial?
A For -- if I have to go to court, yes, sir. It's for 10 hours.
Q But it's $6,000 per day regardless of how much time you spend?
A Yes, sir, if I'm in trial.
Q Do you charge any time for travel?
A I usually travel -- I believe my husband -- I don't do the billing, but I believe we charge for the time in the airplane. If I was working on the plane, then we would charge the $400, but if I'm just flying on the plane, I believe we charge 150 an hour.
Q What is the total amount of hours that you've spent on this case?
A Here, this is... (Deponent hands document to Mr. Hutchinson.)
Q You've handed me two invoices, one invoice Invoice number 2612 and Invoice 2639, and then a handwritten piece of paper that's all within the documents we've previously marked as an exhibit, is that correct?
A Yes, sir.

Q And as best I can tell, you've spent nine and a half hours working on this case. Does that sound about right?
A Before, in getting ready for the prep, because the prep is more than that, going through all the documents.
Q Well, I'm looking at the invoices.
A Yeah, that's what I --
Q So tell me, based on the documents that you've brought with the deposition, how many total hours you've spent in this case from the point you were called initially to before you walked into this conference room.
A (Witness making handwritten calculations.) Thirty-six hours, when you take getting ready for the deposition.
Q I'm sorry?
A Thirty-six hours.
Q Okay, and how many hours do you anticipate spending after we leave today to get ready for trial?
A I don't know. I mean, I don't know if I'm going to be asked to do anything else. I haven't been asked to do anything else.
Q What percentage of your income is working --

strike that. What percentage of your income has been from working as an expert witness within the last five years?
A Um, about three years ago, I stopped doing that much medical device. Mainly I've been doing consulting or manufacturing consulting. So now it's completely litigation support. I'm trying to finish up the cases that I have. So it would be, a hundred percent right now is involved in litigation support.
Q And you've made over a million dollars over the last five years doing litigation work, correct?
A Yes, sir, and I've always been forthright with all my bills. So you have the total. I'm sure, in the records of all the depos, you just put them all together.
Q Do you advertise your services anymore?
A No, sir.
Q You used to advertise on hugesettlements.com, didn't you?
A No, I didn't. Someone else put my website on there and brought it up in a trial. I forget which trial it was, I think a hormone replacement therapy case, they brought it up, and so then I quickly wrote to them to remove it. So no, I did not advertise on that

website.
Q Has it been removed?
A Last I've looked at it, it did, but it's really buried in there. It was, like, you had to know where to look. It's primarily an attorneys' website. It has an awful name, but it's an attorneys' website and so it was really cumbersome to find in the first place, but it came up in a trial and I quickly removed it.
Q Have you ever spoken with Dr. Miklos or Dr. Trepeta?
A No, sir.
(Whereupon, Exhibit 5 was marked for identification.)
BY MR. HUTCHINSON:
Q I've handed you what was marked as Exhibit 5 -- this is off the record.
(Discussion off the record.)
BY MR. HUTCHINSON:
Q Does this appear to be the reliance list for you for this case?
A Yes, sir.
Q And is this up to date?
A It should be, yes, sir.
Q And did you prepare this document?

A I helped prepare the document.
Q Who prepared the document?
A Mr. Lundquist's firm prepared it, but we took it from my documents and from things that I've written for other things, and then I looked at the documents and I tried to determine if it was complete. So I was assisted, but I didn't do the secretarial work.
Q Is the time that you spent on this reliance list reflected in the total amount of time you spent in this case?
A No, sir.
Q Well, I'm sorry, we're going to need to get back, because my impression was that you spent 36 hours total working in this case.
A Working on the case, yes, sir.
Q Okay, but that doesn't include the time you spent on this reliance list?
A I didn't spend that much time on it. If I spend less than a half an hour, I don't bill. So there are times when I could do something very quickly and I don't bill, so the time is not there; and then they would e-mail me something and I'd look at it and I'd say, no, we need to add this, or --
Q Fair to say that you've spent less than -- or

a half an hour or less on this reliance list?
A Yes, sir. I mean, it would be a poor use of my time to be working on that list, but to assist is a good use.
Q What percentage of the materials on this reliance list were supplied by plaintiffs' counsel?
A Well, everything with Ethicon mesh has to come from the plaintiff's counsel. Some of these documents are available, so I would have obtained them, like the guidance documents, the FDA public notes, these are all available information from the FDA. So all the FDA documents were documents that I've -- I obtained, at various different times. So those are all publicly available. So the good majority of it came from me, basically.
Q And I haven't had a chance to look at these black notebooks yet, but are all of these ETH.MESH documents in these two black notebooks?
A The ones that I've relied on should be, yes, sir.
Q Okay. Did you ever ask plaintiff's counsel to get you more documents?
A Not for this case, no, sir.
Q Do you know how the documents that you

received from plaintiff's counsel were selected by he or his firm?
A No.
Q Okay. Did you make any efforts to get any other documents to rely on to support your opinions?
A Well, yeah, the reliance list has a lot of documents that I've got.
Q Such as...?
A The ones that aren't ETH.MESH in my documents that I've obtained, primarily.
Q Did you review any company documents that expressed or provided any evidence contrary to your opinions in this case?
A No.
Q Have you -- let's talk about your opinions for a minute.
A Yes, sir.
Q Have you published any of the opinions that you're offering today?
A Published? Anywhere -- you mean publicly?
Q Yes, ma'am.
A No. No, sir.
Q And I believe we already established that you've not tested -- done any testing of mesh or any

type of mesh product.
A Correct, hands-on testing, that's correct.
Q And how do you define hands-on testing?
A Actually treating a patient or also looking at a mesh in a laboratory, looking at histology, working up mesh issues for Prolene. So I haven't done anything like that. The FDA doesn't do that, and so that's not the process I learned in the FDA.
Q What about any benchtop testing? Have you ever done any benchtop testing?
A Not on mesh. I've done benchtop testing, but not for mesh.
Q Okay. Did you do any type of tests whatsoever in this case that would be reproducible?
A I didn't do any testing.
Q Have you ever spoken with any scientist, engineer or medical doctor about your opinions?
A No, sir.
Q Have you ever spoken to anyone from the FDA about your opinions?
A No, sir.
Q Have you ever called or written or contacted FDA about any of your opinions?
A No, sir.

Q Is it fair to say that all the opinions you have in this case are for litigation and not for any research or study?

MR. LUNDQUIST: Objection, form.

THE WITNESS: At this point in time, that's correct.

BY MR. HUTCHINSON:

Q Okay. Are you intending to offer any criticisms of FDA as part of your opinions at trial?

A No, sir.

Q Why not?

A They're working within the framework in which they can work. So no, the issue isn't the FDA. The FDA -- from what I understand, the issue is Ethicon.

MR. HUTCHINSON: Move to strike as nonresponsive.

Q Do you have any opinions -- scratch that.

Are you offering any opinions to a reasonable degree of medical certainty about Ms. Garcia's medical condition?

A No, that would be cause- -- that's what I would see as causation. Obviously, I think that this device plays into her, but in terms of her physical -- I haven't looked at her records to come up with a

causation opinion. I believe that would be to a treating physician.

Q It would be outside of your area of expertise?

A Well, no, it wouldn't be outside my area of expertise, but it's not what I see as my role. I'm trying to focus it as an FDA regulatory medical officer.

Q Why do you think that would be within your area of expertise, to offer a causation opinion?

A Because I did it at the FDA in terms of health risk assessment, in 21 C.F.R. Part 7. So I did that, and you would come up with issues and look for safety issues, but that's not my role in this particular case.

Q Let's talk about your opinions for a minute.

A And can I clarify?

Q Sure.

A I'm assuming you're asking about standard of care and her treatment and her outcome, and those to me are clinical, and that's why I will defer that to someone who's actually involved with her clinical care and evaluation.

Q Okay, but for the record, you have no opinions to a reasonable degree of medical certainty about what may have caused Ms. Garcia's alleged injuries, correct?

MR. LUNDQUIST: Object to form.

THE WITNESS: Well, I wouldn't say that. I would say that I'm not a causation person that would be a physician talking about her specific case. Obviously, if I'm sitting here discussing Ethicon and TVT Secur, then from a health risk assessment, I believe it's associated with her complications and her outcome.

So I don't know what you would call that in terms of legal term, but it's not primary causation, but is association. It's related in some way to her medical history in terms of her timing.

BY MR. HUTCHINSON:

Q No primary causation opinions about Ms. Garcia, correct?

A I believe that's what we're talking about. That would be for the physicians like Dr. Miklos and the treating physicians to talk about, but obviously, I think there's an association with her symptoms and the types of symptoms that are seen for these devices.

Q Understand. Let me ask you again, so we can have a clear record: You have no primary causation opinions about Ms. Garcia, correct?

MR. LUNDQUIST: Object to form.

THE WITNESS: Am I correct that primary causation would be the medical physician treating the

patient and standard of care? That's not my area of expertise in this particular litigation.

BY MR. LUNDQUIST:

Q And you have no opinions -- primary causation opinions about what may have caused Ms. Garcia's alleged injuries, correct?

MR. LUNDQUIST: Object to form.

THE WITNESS: Well, that's -- in terms of a health risk assessment, I believe that the vaginal mesh is associated, and I don't know what you would call that in terms of legal -- I believe it's associated.

BY MR. LUNDQUIST:

Q Let's talk about the opinions you intend to offer at trial, okay?

A Okay.

Q Tell me, in general, what opinions that you plan on offering at trial.

A Well, shall we go to my disclosure?

Q You know, that might be a good idea. Let me get it. You're looking at Exhibit 4, correct?

A Yes, sir, and it would be specifically page 10.

Q Okay, I'm sorry, I'm on page 9.

A Well, 9 is my history. You want to go to 9?

We can go to 9.
Q Well, that's where it starts, isn't it?
A Yes, sir, but it's really basically background there.
Q Okay, but everything about Parisian on pages 9 through the top of page 14, correct?
A Yes, sir.
Q And does this expert disclosure list all of the opinions that you plan on offering at trial?
MR. LUNDQUIST: Form.
THE WITNESS: The disclosure plus the discussion today in the deposition, because the disclosure's limited as to what it can say, and so my purpose, I believe, for the deposition is that you get to explore what those opinions are that are being listed here in the -- whatever this is called -- in the disclosure. Am I correct?
BY MR. HUTCHINSON:
Q Let's look at -- tell me the best way to boil down those four pages of opinions. So how would you, as a purported expert in this case, boil down your opinions from pages 9 to 13?
MR. LUNDQUIST: Form.
THE WITNESS: Well, the opinions begin where

it says, on page 10, after "Since leaving the FDA...," the next paragraph, "Dr. Parisian will testify that her opinions...," and so we can begin there, because the beginning is my history. You can ask me questions about my history. That's what before that paragraph.
Do you have questions before that, or...?
BY MR. HUTCHINSON:
Q Let's look at -- let's look at page 9.
A Okay.
Q Well, before we do that --
A Because this is your chance to explore my history.
Q Thank you, and before we do that, if -- would it be fair that if I ask you questions about pages 9 through 14 of this expert designation, and when we get to the end of page 14, will we have covered all of your opinions in this case?
A I believe those would be the opinions that I'm planning to give in terms of the court. That's why I worked with Mr. Lundquist to try and make sure you had those opinions, but there's going to be more information and support provided in today's discussion.
Q I understand, but this document would have all the -- your general opinions, correct?

A Yes, sir.
Q All right. Let's look at page 9. It states in the middle, "Dr. Parisian presided over 162 health risk assessments."
A Actually, it was more than that. It was when I was in the Office of Health Affairs, and then I did a hundred more when I was in ODE, so it's 262.
Q For what purpose was that?
A Pardon.?
Q For what purpose was that?
A It was to look at health risk assessments, like I was describing before, about what was the cause; to make recommendations to the FDA in terms of actions to take to protect the public. Many of them were voluntarily recalls, some of them are mandatory recalls. So it would be the processes described in 21 C.F.R. Part 7, health hazard, health risk assessments.
Q And did you do any health risk assessments for mesh?
A You know, I don't know. I don't recall.
Q Do you recall doing any health risk assessments for any SUI product?
A I don't recall -- these are post-market issues, these are products that are already being

marketed, and I don't recall specifically, but it was a while ago. I mean, the last time I was there it was in '95, so out of 262, I don't remember.
Q It states, on the bottom of page 9, you were the FDA's liaison with the National Institutes of Health, involving what?
A For those issues, ENT, ears, nose and throat surgery, kidney, pulmonary, women's health and alternative medicine. So I was -- had to be the person that would go to meetings with the NIH to discuss those issues.
Q The NIH is a very respectable organization, correct?
A Yeah, National Institutes of Health, yes, sir.
Q It's one of the leading authorities in the field?
A It is -- it is, in terms of this country, yes, sir. And in what field? I mean, it is an outstanding medical institution, that's all. I mean, it's... I'm not going to say anything bad about the NIH.
Q When you were the liaison with the NIH, did you work with them on anything about mesh?
A Not specifically about mesh.
Q Anything about SUI?

A I don't recall that I did.
Q Anything about the pelvic floor?
A I don't recall that I did, but I don't recall that I didn't, because about that time there was interest by the NIH on pelvic floor and there was a document that was put out, and I don't recall, because the issue was that I was handling devices for women in terms of medical devices, and so I know that pelvic mesh and pelvic surgery was an issue, and I don't recall what happened with the NIH.
Q Let's look on page 10.
A Yes, sir.
Q It states, in the middle,
"During her tenure at FDA, Dr. Parisian reviewed hundreds of marketing applications for safety and efficacy."
Correct?
A Yes, sir.
Q Those are the 510(k)'s that you reviewed?
A It would be 510(k)'s and PMAs, and then also the investigational device associated clinical trials.
Q Did any of the 510(k)'s that you reviewed have long-term clinical data?
A Yes. The company would commit to follow up,

because they would make claim on the long-term follow-up data. So for industry to make comparative claims, they would come in and say, well, we've done this study, so yes.
Q You've never reviewed a 510(k) for any type of mesh product, have you?
A I don't know, because it's used throughout surgical stuff. So I don't -- I don't remember because I did surgical devices, so I don't -- I did do mesh. I was involved with abdominal adhesions devices that was Proceed, that was Ethicon's product. So I was involved with mesh issues.
Q Okay. Let's talk about mesh for the pelvic floor. You've never reviewed a 510(k) for mesh for pelvic floor, correct?
A Not that I'm aware of.
Q Or SUI.
A Yes, that's correct, because a lot of times, they were using -- at the period of time I was there, they were doing fascia. So I was aware of urological issues, but with primarily with fascia, and they were also doing the sacrocolpoplexy sling and bone anchor, so I don't believe mesh was being used.
Q Did any of the 510(k) applications that you

reviewed recommend -- strike that.
Did any of the 510(k) applications that you reviewed have any labeling that says there was no long-term clinical data?
A Well, there would be nothing that would prevent any 510(k) manufacturer from putting that on. If a device was particularly dangerous -- and I'm trying to think. We had devices that were 510(k)'s because 510(k)'s would cover implanted devices. We would have some kind of statements like that, if there was no long-term data known, because it usually would be a risk versus benefit, that that would be a device, like I can think of devices for, like, handicapped children or something that would be the unknown, that they would have something like that. So there's nothing that prevents that statement, but it's usually a riskier device.
Q All right. Let's go back to my question, okay?
A Okay.
Q Did you review any 510(k)'s that had any labeling, proposed labeling, that says there was no long-term clinical data?
MR. LUNDQUIST: Form.

THE WITNESS: Well, for 510(k), sure, because you don't even have to be cleared -- you don't even have to be making a device to get a 510(k) cleared.
So if it was a risky device, that information would be included in terms of the risk versus benefit for physicians. I don't remember a specific device, but would that be unusual? No, I don't think it would be unusual, particularly if there was no history for the device. But again, it would typically be a risky device.
BY MR. HUTCHINSON:
Q Down there on the bottom, it said, on page 10, it says,
"Dr. Parisian will provide her opinions on the FDA's clearance of TVT-S on November 28, 2005, including concerns with Ethicon's design validation process."
Do you see that?
A Yes, sir.
Q What concerns do you have about the design validation process?
A It's internal concerns by Ethicon. There's -- and I have marked some tabs where they discuss it. If you look at this book, the first book, which we'll call

this one Volume 1, this one that says "TVT Secur," there is a series of documents in here talking about the concerns with quality assurance and the validation process, design protocols. And so there's internal e-mails.

It would begin with tab 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18. So the tabs that I -- in this Volume 1 book describe internally that the company was concerned, particularly their quality assurance people, with the adequacy of the design validation protocol for the TVT Secur device, and that it wouldn't live up to the scrutiny of the FDA if they came in and inspected because of the way it had been done. There were several series of amendments that were made to the design validation. So I'd direct you to those documents, in terms of TVT Secur.

I think what's even more important in that opinion, there, is that I see that, as an FDA regulatory person, my role is to explain the history of how the 510(k) -- to go step back, to explain to a jury the 510(k) process and what it requires, what a manufacturer's required.

So I believe that's usually what -- so you skipped over that part, but I think that's what I would

be giving to a jury is explaining the FDA process and then putting the TVT Secur into that context, of framework.

Q The concerns -- but the concerns that are referenced in this disclosure are concerns that you said you read from company documents, correct?

A Um, the internal concern has to come from the company documents, because --

Q Well --

A -- because this would be privileged information. It wouldn't be out in the real world.

Q Well, I want to know what -- I want to know your opinions about Ethicon's design validation process.

A Well, one that the quality assurance personnel were concerned about, that the company was trying to rush this product to market and they hadn't done adequate testing. They hadn't done design validation, which is a key to a successful device, is that the company, under 21 C.F.R. 820, must do adequate design validation to make sure that the device performs as needed for the patient and the physician.

And so it's a red flag, in a way, when the quality assurance people are concerned about the quality of the design validation that was done before a

design -- before a device is released, and so those would be things that, in terms of good manufacturing, are of concern.

Like, they actually did one design validation where they gave the questionnaires of studies to doctors -- and that would be in tab 11, it would be dated January 26 -- January 3rd, 2006 -- and the doctors' response, when they saw the original study questionnaire, was that they wanted them to revise the IFU.

So even before they had released the product, of the physicians who were looking at this, the product and the performance of the product as part of Ethicon's design validation, were raising questions about the adequacy of the Instructions For Use for doctors.

Q Dr. Parisian, do you know what the design requirements are?

A Sure.

Q The requirements for design validation?

A Sure. In terms of the FDA? In terms of 21 C.F.R. 820? Sure, you have to ensure that your company is making a product that will fulfill user needs, and you have to address any potential risks in terms of the performance of that product, because it's a prohibited

act for you, Ethicon, to market a device that's not safe and effective.

Q On the bottom of page 10 it states,

"Ethicon relied upon two of their own devices, the TVT and TVT-O, as substantial equivalent predicate devices, despite obvious differences between them."

Do you see that?

A Yes, sir.

Q What are the obvious differences between them?

A Um, the obvious differences in them -- well, the length of the mesh, the insertion --

Q The length of mesh between TVT and TVT-O?

A Yes, sir. Okay, because -- and also, well, TVT is a retro-pubic insertion, makes a U-shaped sling, whereas TVT-O is an H-shaped sling, and so both of them had a process where you would have two points of fixation in terms of putting in your sling, yes.

Q What other differences between --

A Well, and so now the company was introducing what they called a single-incision sling, SIS, that had -- was much shorter. It was only 8 centimeters long. So you changed the lengths of the sling.

You had a new insertion device, in terms of,

that had never been used for the TVT or the TVT-O.

You had a new insertion row, in terms of also having to tension this device, because neither TVT or TVT-O required tensioning. So that was a new issue.

So you had a new inserter, you had new tensioning, you had a new release mechanism, you had -- the Ethisorb's fixation was different than had been done with either one of those devices.

So the only thing that's similar is that there was Prolene, but even the Prolene was different, in that the Prolene for TVT and TVT-O was a mechanical-cut Prolene, as opposed to the introduction of a laser-cut Prolene for TVT-S, which changes the stretchability of the Prolene. So there were a lot of differences.

Q Do you know how the stretchability of mechanically-cut versus laser-cut mesh has changed the physiological range?

A The physiological range --

Q The --

A No, no, no --

Q I'm asking --

A Yes, I do know the answer to that --

Q Okay, can you explain that, please?

A -- but I want to explain, the word

"physiological range" came from the company, and it was introduced by the company --

Q Dr. Parisian --

A No, no, no, let me explain.

Q I'll move to strike as nonresponsive.

A No, it was -- yes, I do know the difference.

Q All right, I'm not sure -- okay, then explain --

MR. LUNDQUIST: Let her finish her answer.

BY MR. HUTCHINSON:

Q I'm not asking where the name "physiological range" came from.

A No, it's --

Q What I'm asking is, do you know --

A Yes, I do know the difference.

Q Okay, what's the difference?

A The difference is, the physiological range was to cover the range of the change in stretchability. The mechanical-cut was -- had more stretch, was more elastic than the laser-cut mesh, and so in order to be able to reference the seven years of history with the TVT and the TVT-O, the company created the term "physiological range," even though they knew that the Prolene stretch had changed. They expanded the standard for what would

be the acceptable stretch, to include the TVT Secur.

So it was a term introduced by the company to just cover that we had totally changed the stretchability, we had made it a much stiffer mesh, but that term allowed the company internally, in their documents, to then say, well, now we can recite -- we can use the years of the TVT, but the mesh was totally changed, because you had -- laser-cut edging changes the edge, it melts it, so that you have a much rougher edge than you did for TVT and.... So yes, I do know the difference.

Q Dr. Parisian, are all of the documents that you relied on in support of any opinion about mechanically-cut versus laser-cut within the documents we've already marked as Exhibit 3, or -- 2, rather?

A The one specific for what I'm talking about the physiological range in Ethicon, yes, that's in there --

Q But --

A -- in terms of -- but the issue is, I've dealt with Prolene mesh before, and I know what a laser-cut does versus mechanical-cut, but the documents that would be specifically supporting my opinions about laser-cut are in here.

Q Did you ever review any clinical expert report regarding mechanically-cut and laser-cut mesh and the responses to that?

A No.

Q Okay. Let's look at the top of page 11.

MR. HUTCHINSON: Off the record for a second.

(Discussion off the record.)

BY MR. HUTCHINSON:

Q It states at the top of page 11 on Exhibit 4, "Dr. Parisian will opine on potential flaws of the design of the TVT-S." Do you see that?

A Yes, sir.

Q What is -- what are the potential flaws of design of the TVT Secur?

A Okay. The potential flaws would be the use of the Ethisorb Dura Patch in terms of the attachment end, because that's not -- that's -- and we can talk about why I think that's -- but just to go through my list.

The other one would be the change in the mesh, the stretchability, in terms of decreasing it.

Q You're talking about laser-cut versus mechanical-cut?

A Yeah, that would be one aspect of it. So we have fixation, poor fixation with the Ethisorb. We have

the change in the mesh in terms of the laser cut. We have the tensioning, that the tensioning mechanism is -- has been a major issue in terms of the safety of this device. So there weren't development of instructions on appropriate tensioning.

Let's see, what else? The -- in terms of, the complaints that were being received originally were the inserter was sharp and could cut things, you know, cut organs and cause damage, and then the release mechanism was problematic in terms of the physician knowing exactly where they were releasing. Not only is tensioning hard, but releasing. The physicians and their key opinion leaders said they have a difficult time knowing where they're putting the mesh.

Q Anything else?

A Let's see. 8 centimeters. I think the 8 centimeters, when they go into the design of the next generation mesh, I believe they're doing that around 2008, they're talking about going with a longer mesh because they kind of arbitrarily chose the 8 centimeters based on that it may be acceptable for most bodies, and so --

Q Anything else?

A I'm thinking. Those are the designs. I think

that the reproducibility is an issue with the design, poor design, in that even the key opinion leaders are saying that they were having a hard time predicting what the outcome would be.

So that's an issue with the design, that you want to make sure that it can be used consistently by the physicians if they do it right, and by your instructions, that they will have a good outcome, and so that's a flaw.

Let's see, what else was there? The sheep study. I think the sheep study was a problem. When you go through the sheep study, you realize that they don't do a sheep study simulating use of the product in even the sheep. They do flat pieces of mesh in terms of adhesion, in terms of ability to attach the mesh to the wall with the Ethisorb. They don't simulate a real use situation and the forces of the pelvis.

Let's see, what else? So animal testing would be an issue.

Another issue is that they didn't do a comparison of testing of the TVT and the TVT-O to the TVT-S, and so they're saying that they're substantial equivalent, they get cleared to make a product that's a substantial equivalent, and yet there are issues of

safety and effectiveness that are not addressed, and they got clearance, but once the product gets cleared, they are not addressing safety issues in terms of doing a CAPA and creating preventive types of issues, corrective and preventive issues.

Let's see, what else? And that's not discussing the IFU, because internally there was a discussion that they needed to create a better instructions for the physicians in terms of a cookbook as opposed to the IFU. The IFU doesn't have the same issues that were known in terms of the CER that was written by a Dr. Owens, in terms of a potential risk. None of that information was being provided to the physicians. But that's post-market, so we'll leave that. But the CER was actually pre-market. So they knew those risks and they did not plan to provide those to the physician.

Q Any other flaws of the design of the TVT-S?

A Let me look at tab 8. (Witness reviewing documents.) I talked about the Ethisorb, which is your fleece, and we talked about the stretch in terms of the mesh, we talked about that.

They also changed -- the pull-out force was changed to 164 grams, which was the physiological limit.

They made that change for the TVT-S. Originally, the pull-out force had been around 500 grams. So this is coming from my tab 18, and it's going through the design history of the TVT Secur.

Another issue is that they marketed both the retropubic U and the obturator H as being able to be done with the same device, and that -- that is like, really? You really need to test that out, because you're talking about physicians' ability to plant two different devices, that you supposedly can do it with this device, and I think that -- and that's how they marketed it, and I think even in retrospect, they saw that that was a bad thing to do.

And they say that the placement of this thing is even more -- in this presentation, is even more critical than when you place the TVT, because if you don't plant -- if you don't place it next to the pelvic bone, the pubic bone, you're going to hit the bowel. So you have an issue of potential bowel perforation. You also have an issue with bladder perforation. There was more bladder perforation, so that also is a poor design.

And also, the other products had all been sold as tension-free. So this was now adding tension to the whole mix. I think I talked about tensioning, didn't I?

Q Have we discussed all the potential flaws that you believe were in the design of the TVT-S?

A That's what I'm trying to do. I'm trying to make sure. So we knew -- I had mentioned the 8 centimeters, I mentioned the fixation, I mentioned the correct -- that you need to have the correct placement, and yet, in -- okay, so that's not design. What else?

The versatility; we talked about the sheep study. Okay, those would be things that, before you put a product on the market, should have been addressed.

Q Dr. Parisian, have we talked about all your opinions about the potential flaws of the design of the TVT-S?

A Well, the other big flaw is they didn't do a clinical trial. The pre-market release that they did with Dr. Artibani and Dr. Nilsson came up with safety issues, and the company was going to proceed ahead with the clinical trials, and I think Dr. Weisberg, in his CER, said that they were not going to do a clinical trial based on it being like the TVT and the TVT-O, where internally they're talking about it being different.

Q We'll add clinical trials to the list. Anything else?

A What I'm doing in my answer is I'm generating as pre-market. These are pre-market flaws that you should have been able to see in terms of your risk assessment and your 21 C.F.R. 820, your design flaws. We're not talking about post-market. These are things that should have been known to an expert in this product before they put it on the market.

Q Have we talked about all potential design flaws in the TVT-S, in your opinion, pre-market?

A Well, the other was they relied on engineer Dan Smith, instead of the relying on their own internal physicians, as potential risk.

Q Okay, anything else?

A As for pre-market, yes.

Q Okay, thank you, and these opinions that you formed about the potential design flaws of the TVT-S, those are opinions are based on your review of Ethicon's documents, correct?

A Yes, sir.

Q Anything else?

A Well, I think the other thing that I didn't mention was the learning curve, that it actually -- the company was aware it was difficult for surgeons to put these in to be begin with, and that's a user error

potential problem that you have to put into your design documents and your design validation, and that really wasn't adequately addressed, and when it was given to physicians, they said change the instructions, and they didn't. They kept the same instructions.

So I think, that it was going to be very difficult to put this product in was known before they even launched it in the United States.

Q Let's look at the -- all right. Anything else, Dr. Parisian?

A Um --

Q This is my one and only time to get all your opinions, and I'm entitled to them, so --

A I know, I'm trying --

Q -- I need to ask you. Anything else?

A I'm trying to answer. Well, they worked with Prolene for years, so they should have known about the potential for mesh degradation, that over time you could have mesh degradation. So that was something to also address, because this whole thing is based on the -- and I'm not the pathologist discussing this, but I'm the FDA person -- that the integration of the -- the implant, to hold it in place, is important.

Q Anything else, Dr. Parisian?

A Okay, let me look, let me look. Well, I think --

Q And let me ask you this. What are you reviewing now?

A Here, you can see. (Witness indicating.)

Q You're reviewing your expert designation, correct?

A Yes, sir.

Q Okay.

A And I'm trying to kind of shorten it, so --

Q Sure, if you can shorten it so we can move on, I'd appreciate it. Anything else?

A The other issue I think that the company needed to take into consideration was that they were already marketing the TVT and the TVT-O, and so those devices actually had a potential risk for erosion; so the complications, dyspareunia, vaginal scarring. So there was a known risk associated with these types of device. They didn't just begin one day and make the TVT Secur. So those elements that were already known, if you're going to make a less-invasive, safer device, should have been addressed in their early testing and design, and they didn't.

Q Anything else?

A Yeah. Before they even marketed this device, they did have the pre-market information from the physicians who had done it, and there was no plans to have a certification training to make sure that the doctors were aware of how to use this product.

Q And that's a potential design flaw with the design, correct?

A From the very beginning, that there was nothing put out that they were going to address it. As, like I said, they already had the history of the TVT, the TVT-O, so --

Q And any --

A -- insertions is important.

Q Move to strike as nonresponsive. Anything else, Dr. Parisian?

A I think that will do it.

Q Okay. Look at page -- at the top of page 11.

A Yes, sir.

Q It says,

"Dr. Parisian will also discuss the adequate and ethical disclosures required when ghostwriting articles."

Do you see that?

A Yes, sir.

Q What do you mean by that?

A Well, that in terms of, you have to -- well, I would specifically refer you to my book, in terms of tab 6 and tab 7. Do you want me to pull those out, in terms of ghostwriting?

Ghostwriting refers to -- let me get that, 6 and 7.

Q I'm not asking about what ghostwriting refers to. What I'm asking is: What are your opinions about adequate and ethical disclosures required when ghostwriting? So if you can stick to that question, I'd appreciate it.

A All right, but for your benefit, I'll reference to you tab 6 and 7, when you have my book.

Ghostwriting ethical is disclosure. The company needs to inform the physician, or the patient, the source of the information that they're -- that they're providing.

They have to also disclose their involvement in writing a report. For example, the sheep study was put out, published, and Dr. Artibani says they hadn't been involved in it. He was basically put on the article as a name, and Dan Smith, who had actually done the sheep study involved at this time, was only put on

as a "thank you for helping."

Q Okay, anything -- would you give me another example?

A Well, and also, those would be under the regulations, in terms of writing adequate instructions and adequate warning, adequate information about the product. Where is this information coming from?

And so that's required, in terms of ghostwriting, that a company disclose that to a physician, and particularly if they're going to using it as their marketing information that they're going to have their sales reps give out, and so that would be under your 21 U.S.C. 352 and adequate instructions, adequate warnings.

It would also feed into --

Q Dr. Parisian, let's stick with answering the question.

MR. LUNDQUIST: She's answered your question about the ghostwriting.

MR. HUTCHINSON: I know. I'm asking, for example, she gave me the Artibani sheep study.

Q What other examples?

A All right, well, there's the performance evaluations of a new TVT-like mesh system for the

treatment of stress urinary incontinence. It's in my tab 7, and it basically says, we need to get two surgeons as lead authors, otherwise there's a little credibility leak for customers.

So Ethicon is writing an article to be published about the use of the TVT mesh system for SUI, and they're including the TVT Secur -- they're saying how -- this is -- this example is for TVT, and they're proposing --

Q Okay. It's not for TVT Secur, correct?

A Well, that's correct, but the page says, "would suggest something like performance evaluation of this for TVT Secur."

So this is an example of the company writing an article, they say they're going to find doctors' names to put on the article, and they're talking about that they would like a similar type of article for TVT Secur.

So this is an example of ghostwriting, and this is an example where there's not a disclaimer that the company has written the article, and that the -- they're just going to find doctors to put the names on.

Q Can you give me --

A That's ghostwriting.

Q Excuse me. Can you give me any other examples?
A Well, I gave you those two examples, talking internally.
Q Well, can you give me any other examples?
A Well, those are the two I have.
Q Other than those two.
A There is, I believe... (Witness reviewing documents.)
Q And Dr. Parisian, just for the record, when I'm asking for examples, you're looking under tab 6 and 7, correct?
A I was. I'm looking right now at tab 4, because of the -- the plan for how they're going to release the product.
Q Can you give me any other examples, other than the two that we've already discussed?
A That's why I'm looking at this one document, to see if they talk about those -- getting publications out, but I don't -- I don't see that they do. So those were the two that I'll stick with.
Q If you look on -- further on page 11 --
A Um-hum.
Q -- kind of in the middle, it states,

"Dr. Parisian will also testify that Ethicon failed to adequately study, design and test the TVT-S prior to allowing the device to be sold."
Do you see that?
A Yes, sir.
Q Have we already discussed all of your opinions relating to the adequacy of studying, designing and testing the TVT Secur? I think so, but I just want to make sure.
A That's the pre-market, but then it goes on to talk about the post-market.
Q I understand, pre-market. Have we already discussed all of your opinions?
A About the potential flaws of the design.
Q Of the study, design and testing of the TVT Secur, in pre-market.
MR. LUNDQUIST: Objection.
THE WITNESS: If I divide it into pre-market, and then the next part of that paragraph --
BY MR. HUTCHINSON:
Q I'm sorry, is that a yes?
A Let me think about it. Yes, I think that would be the -- well, the tests would be the clinical

trials that they -- there wasn't a plan to do clinical trials before they launched, or to do a human trial, or even to do a sheep study that simulated the use.
So that would be testing, as opposed to the flaws. The design flaws were the obvious issues that they needed to -- but even their testing was inadequate. So that's little bit more.
Q Let talk about post-market. What do you believe -- what are your opinions as to what Ethicon failed to do on post-market of the TVT Secur?
A Well, in terms of post-market, they weren't actually -- they didn't get any clinical data on the post-market failure. Most of these devices, when they failed, they were failing in 12 weeks.
I went and did an MDR search, and that's not in here, but it was part of this type of an opinion, and Medical Device Reports are described under 21 C.F.R. 803, and they're mandatory for Ethicon when they receive information about a failure of their device, return of SUI, erosion. Those would be failures.
If you look at the MDRs, the Medical Device Reports, and you look at the reports that are being discussed internally about the failures, they're not consistent.

I went and just, last night, quickly just put in "TVT Secur" -- if I can find that document --
Q Well, why don't you stick with me. On post-marketing opinions --
A Well --
Q -- the first one is no clinical data, correct?
A Well, yeah, this is essential to post-market, because this is --
Q Okay.
A -- mandatory.
Q Are we on the second opinion?
MR. LUNDQUIST: She's talking about her -- she's still articulating her point on post-market issues, I think.
THE WITNESS: Yes.
BY MR. HUTCHINSON:
Q All right, we're back.
A Post-market requires -- when I say post-market, that would include complaint file handling, and this would be all described under 21 C.F.R. 820. It would be complaint file handling as well as medical device reporting.
So internally, the documents, I see discussions of failures in Germany and Australia, and

that information is not being filed with the FDA, and it should be, because that information is not -- unless the company is feeling that they don't need to file because it's already in their labeling, okay, in their IFU.

And so if you look at -- which it's not -- if you look at the trend -- okay, I did a really, really fast look at the Medical Device Reports last night, because this is a discussion about post-market, and I felt that I needed to look at the MDRs to see if the company was filing MDRs, because they're required to when they find out that the product failed.

And when I looked at the years 2006 through 2007, which is a year block, for Gynecare TVT, there were no reports in the FDA's database of anything, okay? So -- and that's all the TVT products. There's nothing.

And then when I did a look at year -- on the back of this page, you may want to have -- be aware there's information on the back.

Q This is handwritten notes by you, correct?

A Yes, sir.

Q And this is in what we've previously marked as Exhibit 2, correct?

A Right, but it's on the back, so somebody may miss it.

Q We'll make sure we have it, and what is this?

A This is -- so my computer wasn't working very well last night, so that's why I didn't print it all out, but I went and I looked at the years 2007 to 2008, for all Gynecare TVT, all products, and there were three MDRs filed with the FDA. Only one of them was for Secur, and it was filed not by the company but by a user facility, and I printed it out, and it was for a bent device. It wasn't for a patient injury, it was a bent device that the doctor had, and they had to send it back. So there were three, a total of three MDRs.

Then I looked at the year 2008 and 2009. There were nine MDRs for all of TVT. Two of those were for Secur. So 2008, 2009.

Now, internally we're seeing discussions of Germany and Australia, failures for people like Lucente, and they're not being captured in the MDRs. They should be, because the IFU and the labeling doesn't have the severity and the frequency with which reports of erosion, dyspareunia is occurring and failure. So that information would be required to be reported to the FDA, in terms of the regulations, 21 C.F.R. 803.

Year 2009 through 2010, there's eight reports, and there is one Secur report in those eight, and it was

from a user facility, not from the company.

The year 2010 through 2011, there were nine reports, and I believe there was one report for Secur, where there was an erosion, and the company said it was because the doctor implanted it too tight for the Secur, and that the woman had had severe pain, on antibiotics for two years, numbness both legs, incontinence, and so that was reported to the company supposedly in 2010 for an implant of 2008.

When you look at 2011 to 2012, there's 18 reports, and the Secur report is actually voluntary, it's by somebody else, for an event from 6/1/2007, where a woman was complaining in one week post her surgery she was incontinent.

Okay, and then you look at 2012 to 2013, and there are 22 records, of which five of them are Secur. So FDA is not getting a lot of MDR reports here from the company up through 2013.

Then 2013 to 2014, after Ms. Garcia's procedure, there is over 500 records. I didn't look at all of them because it was late, but there were over 500 records.

So the FDA is not getting reports for anything for TVT really until the year 2013, and there were 61 of

those 500 I counted were Secur, which is a small percentage, really, of over 500 reports. I could go month by month and find out what the total would be, but I think it makes its point, that FDA was really not getting Medical Device Reports from the company until 2013, and yet their records show that they were aware of issues before that, and they're not getting a lot of reports for Secur.

I mean, in 2013, they have 61 reports out of 500. That's a small percentage that's Secur. The year 2014 to 2015, there's 500 records.

So if you're going to say that they're required to report Medical Device Reports to the FDA to notify the FDA or alert the FDA of a safety signal or an issue with their product, there's no signal here for Secur until -- or anything with TVT until 2014, 2013.

So they're not filing MDR reports as they're required to do, and if a physician knew how to look up MDR reports, say, any physician who decided, I'm going to use this device versus another, the MDRs really are fairly silent. There's not a lot of reports. So I think that feeds into that opinion.

Q All right. Dr. Parisian, have we discussed all of your post-marketing --

A No, no, that's just getting started.
MR. HUTCHINSON: All right. Well, I'll tell you what. I'm going to -- and we'll -- I told everybody that at the beginning of this deposition that I'm trying to be respectful for the witness' time, but we're just simply not going to finish today if we continue down this path.
So I'm going to ask, Dr. Parisian, if you would, just in an effort for me to be respectful for your time and your -- Mr. Lundquist's time, if you could stick with my question, so we can kind of move on.
MR. LUNDQUIST: And hold on, Doctor.
I mean, with all due respect, Chad, you're asking a pretty broad question, on the -- you're asking her the basis for her opinion. She's given it to you.
MR. HUTCHINSON: Okay.
MR. LUNDQUIST: I think she's being actually fairly as succinct as she can, over a six-year period, with some of these MDR reports. And to be clear, I mean, we will be finished today after six hours on the record. If you want more time, obviously, you have to take that up with the judge.
MR. HUTCHINSON: Okay.
MR. LUNDQUIST: But if you want to ask her

more specific questions, perhaps --
BY MR. HUTCHINSON:
Q Doctor --
MR. LUNDQUIST: You understand where I'm coming from, as well.
BY MR. HUTCHINSON:
Q Dr. Parisian, your opinions on post-marketing surveillance relates no clinical data, the filing or not filing of the MDR reports. Any other opinions?
A Yes. In 2007, the German complaints they received, January 2007, my tab 49, they received complaints from Germany of 49 reports of failures, at four to 12 weeks.
They also had complaints of Australia, the Australian issue in 2007, that they were having problems in Australia with the three key opinion leaders in Australia having a 65 percent failure rate, a 30 percent failure rate and a 45 percent failure rate. Those were post-market, because this is the performance of the device in human beings outside the United States.
Q Anything else?
A So, yeah, Germany, let's see... I would say also the European experience that the company had in 2007, talking about that the -- and this would be under

my tab 45, this is a presentation May 15th, 2007 at the European Feedback Board Update, and the company's talking about the failure rates in terms of the TVT Secur. They knew that the TVT-O had had a failure rate from early experience of 89 percent, whereas the TVT Secur was 74 percent. They knew the Monarc was supposedly 91 percent.
They talk about the things they knew about the device and the problems with it. The issue of tension was discussed in that meeting. They said that there's large variations of the surgical procedures. They said results on incontinence are not consistent with 70 percent rather than 90 percent, results were unpredictable. So that would be another example, with the European experiences.
They were saying that in 2007, that the key experts and nonexperts are disappointed with the product and are abandoning the procedure. They said that there was no advantage over the conventional TVT and to accept these failures that they're seeing. They're already talking about coming up with another device, Dr. Leval's mini TVT-O. So that's 2007.
The Australian would be around.... So internally, they were getting information that the

product was having problems.
Q Anything else, on post-marketing?
A Okay, let's see. Well, again, this would be a document that was -- we're talking about what happened -- what did they have before June 2010 on Ms. Garcia's surgery.
Q No, I'm asking you about any other opinions about post-marketing.
A No, but I tried to testify on that particularly. So there is a presentation, Incontinence Platform, August 19th, by Harel Gadot, which would be also in Europe, and he's talking about the International UGA abstract, that there was de novo urgency reported in the abstracts, and 4.2 percent voiding dysfunction.
So there was information from Europe Dr. Lucente experienced at six weeks. He had -- he was having a high failure rate, and that's Dr. Lucente, who's one of the key people for this product. They know that there's a huge -- that the learning curve is great. So this is all post- -- this is all post-market issue.
And this is where they say in the presentation, "It is completely different than the TVT and the TVT-O." That's significant, because the 510(k) cleared it to be marketed only because it was

substantially equivalent. So internally, the company's aware from the European data that it's not a substantial equivalent. That would then make it by definition an adulterated device. It wasn't the device cleared by the FDA.

Q Anything -- any other opinions regarding post-marketing surveillance?

A Okay. User error is a post-market issue, and they have --

Q Okay, tell me about your opinions about user error, please.

A Tab 41 begins with the Germany experience, poor experience in tensioning, and then tab 42, March 2007, there is discussion about the learning curve, longer learning curve; mesh tensioning was different than any of the other kits. Tab 42.

Tab 43, which is a March 2007 e-mail, early results of TVT Secur, they're saying that the tension isn't tight enough. So tension, 30 percent recurrence, that I know about, in terms of that tab, early results of TVT Secur. And the salespeople are -- in Europe are asking about the rumor that there's 30 percent incontinence.

Q And -- sorry.

A So those are post-market.

Q Any other opinions about post-market, Dr. Parisian?

A Well, I would definitely send you to tab 44, which is a PowerPoint presentation called "TVT Secur" before the Quality Board.

Q Yeah, I'm not -- I'm not going to get to the documents that you looked at. I just want to know what your opinions were on what Ethicon did wrong in post-marketing.

A Okay, well, they weren't filing MDRs. They weren't doing a corrective and preventive action to correct the issues that are being described when they know their product's not substantial equivalent. Can't do that under 21 C.F.R. 820. So you can't market a product that you have all these signals from post-market that it's not performing like you're cleared.

Q Anything else?

A Well, in terms of post-marketing, in terms of Australia, where they're having problems, the company says, in this Quality Assurance -- Quality Board presentation, that despite knowing that the product is failing in Australia and there's an issue, that they're going to keep the product in the market in order to

train people.

Well, you don't do that. If there's a user error or problem, you don't just allow them to continue to use it to keep the product on the market.

Q Anything else?

A They didn't conduct a recall in the United States. When they knew that the product was not performing as it was cleared, and it was adulterated and it wasn't safe and effective, they didn't stop sales, they didn't contact physicians, like Dr. Miklos, Dr. Walss, and let them know about the potential risks with this product, particularly for the women who were implanted already, and they continued to market a product that was defective, basically, in terms of 21 C.F.R. 806. It should have actually been -- marketing should have been stopped. There are plenty of other products.

Q Anything else?

A That you continue to market an adulterated device?

Q Yes, ma'am. Anything else, any other opinions related to post-marketing?

A Well, in all that post-marketing, they also knew the pre-marketing flaws, in terms of what I had

originally said about their design, testing, sheep.

So that should have all been something that should have raised a red flag, because they knew the background of this product, and the other products. So they should have incorporated a comparison of the products already being sold into their post-market.

So you didn't have notification of physicians. You didn't have notification of the FDA, because you didn't have MDRs being filed. You didn't have FDA being told the product isn't performing the way it was supposed to. You had continuing marketing of a product that was not -- that was not performing the way it was supposed to. You didn't have updating of the IFU to inform people of the risk of the frequency.

Q Okay.

A You didn't have updating of the IFU in terms of CAPA, as to which patient should this be used for, because they make a claim to the FDA that it's only certain patients, and in Australia they're proposing, well, maybe we'll tell the Australians it's obese women or really healthy women. So they don't narrow down who is this device for --

Q Okay.

A -- and is there any benefit of this device.

And so I think notification, continued marketing, no reporting, failure to correct the problem --

Q Anything else?

A That's quite a bit. Let me think about that.

Q All right. Have we discussed all of your opinions as they relate to the pre-marketing and post-marketing of TVT Secur?

A Let me look at this a minute. Well, I think my other opinion is that this product wasn't going to work. I mean, they didn't convey to physicians this unpredictability, and I think Dr. Miklos will actually testify about that more, but it was, like, Dr. Walss and all other physicians using this product were doomed because, for one, they say there's a learning curve; some people say there's over a hundred patients; they don't have good instructions in terms of tensioning.

There's no way that you could use this product -- the KOL, the key guys, in 2006, were having a hard time using it. So if the key users can't use it reliably, then who -- what other physicians are going to use this product?

So it's failing of the company to tell the doctors that this is a really risky product and there's a high risk, and do you really want to use it? And

I think that my tabs for that would be tab 48, tab 47, tab 49, tab 53, 54, and 58, and then also Dr. Miklos, because he had been a preceptor, and he said how difficult it is to place.

So it's like -- it's like getting a product with -- from Home Depot with Chinese instructions, and no one's ever going to put it together, and that's basically what's happening, and so it's getting blamed on user error, but there's a point where it's not user error, it's design error that's also contributing to the user error, and so that goes back to design flaws of the pre-market.

Q Have we discussed now all of your pre-marketing and post-marketing opinions and the bases for those opinions?

A Well, the other one would include that post-market, they're not informing the FDA. So that's actually kind of its own opinion.

Q Have we now discussed all of your opinions, as they relate to the TVT Secur?

MR. LUNDQUIST: Post-market or pre-market? Yeah, okay.

THE WITNESS: We didn't touch on the user brochure. In my book, there's a patient brochure, and

that needs to be included too, because the patient brochure was -- the one I have is generated in 2008, and it says, if -- the only number in there is 97 percent. So for TVT family, it says that you're going to have a -- it implies a 97 percent success rate.

So if a woman received such a brochure, it doesn't have adequate information about risks or warnings, in terms of the differences in the risk for a TVT-O versus TVT, versus a TVT Secur. That information is not in there. They just put them all together as a TVT family, and I think that's misleading in terms of 21 C.F.R. 801.109, that's adequate prescription labeling, and FDA uses that also to apply to a direct-to-consumer information.

BY MR. HUTCHINSON:

Q And that's --

A So you have to be truthful and accurate there.

Q I'm sorry. Are you finished?

A I think so.

Q Okay. Have we now discussed all of your opinions as they relate to the pre-marketing and post-marketing of TVT Secur and the bases for those opinions?

A Well, we haven't talked about bases. You

haven't wanted me to go through the bases, but these are my opinions as to them. We've talked about what my opinions are, and then I've been trying to lead you to the bases, but we haven't discussed those.

Q Okay, well, I need to find out all the bases for your opinions, too.

A I know. I've been trying to provide it to you.

Q Well, if you could -- if you could do that for me, I'd appreciate it.

A Well, that's why I'm trying to give you the bases in terms of the tabs --

Q Okay.

A -- so you know which documents I'm looking at, and we can go through those documents specifically, but I was trying to shorten it, to give you the opinions.

Q Okay.

A That's what you asked. That's what I understood you to ask.

Q Okay. Have we now discussed all of your opinions as they relate to the pre-marketing and post-marketing of TVT Secur?

A Well, I also read Dr. Walss' testimony and I think my opinions are relevant in terms of his use of

the choice of this product to implant in Ms. Garcia, to bring this back to Ms. Garcia; and also Dr. Miklos. I think they're consistent with what Dr. Miklos says in terms of his understanding.

So the post-market are further supported in Ms. Garcia's case by both of those physicians, in terms of their experience with these products from a clinical standpoint.

Q Okay. Have we now discussed all of your opinions as they relate to the pre-marketing and post-marketing of TVT Secur?

A As topics. We can go through specific documents and I can show you the basis for each one of those opinions.

Q But as topics, we've covered them all, correct?

A I've been trying to summarize it all into -- let's see. In terms of the post-market, I think the Australian is important, and it's another opinion, in that the FDA wasn't told about the potential risks for Australia. The company never conducted a recall in Australia. They had a Dear Doctor letter, so that they were going to update training. Physicians didn't want retraining, and the company was thinking about

introducing this product to block off the Miniarc.

And that information, FDA's required to have that information, too, in terms of post-market safety information about a product that's being marketed. That would be significant to FDA, that the Austr- -- human data, no matter where the source, is significant to the FDA in terms of safety, patient safety, because when products are cleared, there's little human data.

And so the Germany experience and the Australian experience should have been told to the FDA in some fashion.

Q Okay.

A And it wasn't, and so that also would be misbranding of your device in terms of 21 U.S.C. 352(t), small T, that you have to provide reports to the FDA, and that would be information that needs to be safety information, even for a 510(k), that needed to be communicated to the FDA, whether it was MDRs or it was just direct notification of the FDA.

Q Have we now discussed all of your opinions?

A And also, more importantly, as Dr. Walss said, that would have been important to him to have known about, and also Dr. Miklos; so not only to communicate it to the FDA, but to communicate it to the physicians.

Q Have we now discussed all of your opinions --

MR. LUNDQUIST: Form.

BY MR. HUTCHINSON:

Q -- as to the post-marketing and pre-marketing of TVT Secur?

A There's a lot of opinions there.

Q I'm not asking you how many, I'm just asking if we've discussed them all.

A Let's see. I'm trying to... Well, in post-market, I think there's also, I believe, in tab 44, when they're talking about the challenges, lessons learned, the company as part of their post-market --

Q I want to talk about your opinions, not what the document says.

A No, the opinions --

Q Tell me what your opinion is.

A The opinion is that the company identified that the rush to market without clinical data was a significant factor in terms of the failure of this product in terms of, to succeed. So that would mean that the company identified that as a post-market issue, that they weren't going to do that in the future is what they said, and that would come out of tab 44, and they said that in 2007, years before Ms. Garcia was

implanted.

In tab 50, the company was aware that it was suboptimal performance.

Q Do you have any other -- I'm sorry.

A Yeah, and then the marketing, we haven't talked about the marketing, because marketing actually would fit under post-market issues too, in terms of the information that the physicians were being told about the success and performance of this product, that was not acceptable too. The claims that were being made for this product as being less invasive, less risky, it's implying it's a safer device and it's not, in terms TVT-O and TVT. So marketing is another issue.

So we have physician notification, FDA notification, we have a learning curve, training, tensioning, we have marketing claims, we have failure to communicate risks even to patients, doctors, and failure to file MDRs, failure to make effective CAPAs, in terms of quality assurance, continuing to market an adulterated device, prohibited act, 21 U.S.C. 331(a) and (b).

Also, and we haven't talked specifically about the IFUs. We'll talk about that.

Q We'll get to the IFUs in a minute, but is that

a fair summary, what you just gave, of all your opinions as related to the pre-marketing and post-marketing of the TVT Secur?

A Yeah, and then what they had learned --

Q And I'm sorry, is that a yes?

A I think so, and what they had learned in terms of the next generation, which was, by 2008, they're already talking about what they were going to do with the next device.

So there is this post-market where they're moving on to another device already before Ms. Garcia is implanted, and then -- let's see.

Also the communication with the FDA in terms of the 522, not doing the 522. The communication is not that this is -- we're taking this off the market because it's a dangerous device. The company told the FDA, supposedly, based on the company's documents, that it was a safe device and we were just making a marketing decision, and it's not accurate. That would fit into the FDA reporting.

Q Okay.

A But they didn't get a 522, and then they closed the registry, in terms of post-market information. They had opened a registry, they knew they

needed clinical data, and they closed it prematurely, without the data, and we don't have the follow-up to what happened to that registry data. So that's another post-market issue.

Q So have we now discussed all your opinions as it relates to the pre-marketing and post-marketing of the TVT Secur?

A I think also, I would reference Dr. Miklos' report --

Q Well, instead of referencing reports, I want to talk about your opinions.

A Yeah.

Q Okay.

A But --

Q So why don't you tell me: Have we discussed all of your opinions as they relate to the pre-marketing and post-marketing of TVT Secur?

A We have discussed my opinions other than the IFU. I said we haven't specifically discussed the IFU.

Q All right, thanks.

Your lawyer -- I mean, I'm sorry -- Ms. Garcia's lawyer has asked to take a quick bathroom break. So why don't we go off the record for just a second.

THE WITNESS: That would be fine. I'd like that.

(Deposition in recess from 10:55 a.m. to 11:04 a.m.)

BY MR. HUTCHINSON:

Q Dr. Parisian, we're back on the record. You realize that?

A Yes.

Q Are you ready to go?

A Yes, sir.

Q Okay. Now, you're a pathologist, is that correct?

A Yes, sir.

Q Last time you treated a living patient was when?

A In the 1980s. I was a company doc.

Q You're not a member of the American Medical Association?

A No, no, I am.

Q You are?

A Yes.

Q How long have you been a member of the American Medical Association?

A For years.

Q More than 10 years?

A More than 10 years, yeah.

Q Okay. Have you ever been board-certified in internal medicine?

A No, sir, just pathology, anatomic and clinical.

Q Do you have any staff privileges at any hospital?

A No, sir.

Q Are you credentialed at any hospital?

A No, not right now. I'm licensed, but not credentialed.

Q You're not a biostatistician?

A That's not my training. I've used biostats for different issues, but I'm not -- that would not be what I would put myself out as.

Q Or an epidemiologist?

A Only in that I've done epidemiology for the FDA. I have hands-on epidemiology, but I don't have a degree in epidemiology.

Q But you're not holding yourself out as an expert in epidemiology, correct?

A Not for this litigation.

Q Or a toxicologist?

A I've been trained -- I can run a toxicology

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lab as a pathologist, but I'm not discussing toxicology for this litigation. I've had no toxicology in terms of FDA.

Q You're not -- I'm sorry.

A Well, because I had to look at animal data. They didn't -- as a pathologist, they used me also to do a lot of toxicology work for devices.

Q You're not a polymer scientist, biomaterial engineer or behavioral scientist, correct?

A Those aren't my specialties. I've been involved in all those issues.

Q You're not a surgeon?

A That is correct.

Q Not a gynecologist?

A Well, I did a lot of gynecology in terms of general practice. So I've done it as a family practice-type situation, but I'm not a gynecologist.

Q What about a urologist?

A No, I'm not a board-certified urologist. I've done some urology. I mean, I'm assuming you're talking about someone that's your specialty every day. Yes, I am not a practicing urologist.

Q And you're not a urogynecologist, either, are you?

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A I'm not a practicing urogynecologist, but I'm a pathologist. So in terms of the anatomy, I'm aware of the anatomy and the issues about it.

Q You're not an expert in SUI?

A Only in the regulatory issues for SUI. I'm not a person who would treat patients for SUI.

Q Not in the medical sense, correct?

A Yes, correct.

Q And in fact, you're not an expert in any of the medical specialties that may be at issue in this case, correct?

MR. LUNDQUIST: Object, form.

THE WITNESS: I'm an FDA regulatory expert. A pathologist does have some role. I'm not your pathologist, there's a pathologist, but I have that clinical training and background as an FDA medical person.

So I don't know what you're -- I mean, I'm not -- I'm an FDA medical officer. So I'm talking about regulatory issues for a medical device in a particular case, so --

BY MR. HUTCHINSON:

Q Well, I'm asking you if you're an expert in any of the medical specialties that are at issue in this

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case. Medical specialties, not FDA regulatory, medical specialties.

MR. LUNDQUIST: Form.

THE WITNESS: The medical specialties would be anatomic clinical pathology, but I'm not -- that is not my sole role here.

BY MR. HUTCHINSON:

Q And you're not an expert in determining corporate motive or intent, are you?

A I wouldn't even do that. The only thing I would use is documents that state what the intent or motive is, not a subjective intent or motive, that's correct, but what the documents in evidence support, or what their testimony is. That would be them saying what their intent was.

Q Do you know what the current gold standard for the treatment of SUI is?

A No, not -- I don't know right now what today it is, because there's a lot of options, and also the SUI can have -- the degree with which the woman has SUI would determine the options, whether she goes through in surgery or whether she goes to minimally invasive or whether she doesn't get anything now and uses Kugel exercises, just those with pads. So I don't know what

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the gold standard is.

Q Are you familiar with the American Urogynecological Society or the American Urology Associates or Association, or the International Urogynecological Association?

A I'm familiar with the words and what they've done and their involvement in some of the SUI issues.

Q Are they well respected societies within the field?

A They are the societies for the field. Well respected by who? I mean, there are people join them. Some of those fields actually had begun some of the concerns about SUI and mesh products.

Q Would you consider them leaders in the field, these societies?

A They are societies for those fields, so there's nobody -- so they would be the leaders for those fields, because they're professional organizations.

Q Would you consider them well respected?

A Yeah, doc --

Q Within the medical community?

A Yeah, I have no reason to -- I mean, it's like the AMA. Is the AMA well respected in the medical community? It's a professional organization. People

join it.
Q And you relied, in reaching some of your opinions, in part, on some of the literature from these societies, correct?
A Yeah, and some of their meetings and some of their concerns, when they were concerned, I think around at 2006, about the safety of surgical mesh. They actually were bringing it to the forefront. FDA actually was responding to the specialists who were concerned about SUI and pelvic floor replacement, POP procedures.
Q Have you ever diagnosed, treated or managed SUI?
A Yeah, sure. I mean, I've had women with SUI, and you tell them what it is, and you talk to them about what the options would be, and just -- that was back in the 80's.
Q And you did that when you were a pathologist?
A No, when I was treating real people, living patients, back in the 80's. I was the company doctor at Avtex, and I was the first -- you would have patients come in and they would explain what their problems were, and then I would have to send then to somebody else, refer them. So yeah, I would have to talk to them about

SUI.
Q Right, but you never managed a patient with SUI or treated a patient with SUI, did you?
A I would have referred them to somebody or told them what their options were. Oftentimes they chose not to do anything.
Q Have you ever participated in a cadaver study or an animal study about mesh?
A Not about mesh. I've participated in a lot of cadavers, but not about mesh.
Q Anything about any foreign SUI product?
A Pardon?
Q Have you ever participated in a cadaver or animal manual study for any type of product?
A I didn't participate. I've consulted for manufacturers who was working with the product they wanted to get cleared.
Q Have you ever seen how a TVT Secur product is implanted in the body?
A Physically seen it, no.
Q I take it you've ever implanted a TVT Secur device in somebody's body.
A You are right, I never have.
Q And nor have you implanted any medical device

in any person's body, correct?
A Um, I don't know if I have. I mean, I put sutures in people. I mean, I've done lacerations. I don't know if I've never -- I've assisted when they've implanted devices. I've not been the primary implanter of, like, a hip implant or something like that.
Q And do you have any expertise in implanting medical devices in any way?
A I don't know, because you're talking about a history going back to the 70's, and so I don't know.
Q Okay.
A Um, medical devices -- I mean, I wouldn't say I'm a cardiologist, I didn't do pacemakers, so I didn't do any specialized devices, but to say I've never implanted a medical device, I don't know.
Q Do you -- well, that's not my question. My question was, do you have any expertise in implanting medical devices?
A From the regulatory point of view --
Q I'm not asking for the regulatory, if you don't mind, I'm asking for a medical standpoint. Do you hold yourself out as having expertise in implanting medical devices?
A I've been around where medical devices -- I've

been in the OR when medical devices are implanted and I've also removed medical devices after they've been implanted. So I do have some hands-on expertise about the biocompatibility and the effect in the body of medical devices. I don't have a specialty that had a specific device that they're implanting for a procedure, but the working parts of the body for implantation, yeah, I'm familiar with that.
Q Have you ever designed any clinical trials regarding mesh?
A Not for mesh.
Q Any type of SUI product?
A I did not design it. I reviewed it. So that was the radiofrequency trials.
Q You've never been involved in any clinical research regarding mesh, have you?
A No.
Q Or SUI?
A No.
Q You've never designed pelvic mesh?
A No.
Q Or any type of SUI product?
A Only consulted on someone who was working with one.

Q And I think we talked about this earlier, but you've never done any type of biomechanical testing for pelvic mesh or any SUI product, correct?
A Correct. FDA wouldn't do that.
Q In fact, you've never inspected a mesh explant, have you?
A Yeah, I've done that. I mean, I've seen explanted mesh.
Q Have you ever inspected -- I'm not asking if you've seen one, I'm asking if you've inspected one.
A Well, I've -- surgical path, you remove explanted mesh. I don't know what you -- I meant looked at it and examined measured it and the qualities of it. I don't know what you mean by "inspect."
Q Did you ever inspect -- well, did you ever inspect a piece of mesh for any types of degradation? Have you ever done that before?
A Not in the laboratory setting specifically. I would be looking at it grossly.
Q You've never performed a DDSA, have you?
A No.
Q You've never performed an FMEA, have you?
A Wait a second, wait. Go back. The DD -- what did you say?

Q DDSA.
A Yeah, what are you saying is a --
Q Do you know what DDSA stands for?
A I don't know what it --
Q What about a Design Device Safety Analysis, have you ever --
A Oh, that, yes --
Q -- performed a Design --
A -- but I haven't used that term for it.
THE REPORTER: Wait, one --
MR. HUTCHINSON: Wait a minute, one person at a time.
THE REPORTER: Yeah, one person at a time.
BY MR. HUTCHINSON:
Q Have you ever performed a design -- I'm sorry, scratch that. Have you ever performed a Device Design Safety Analysis for a mesh product?
A Not for a mesh product.
Q Or any type of SUI product?
A I've reviewed the ones that the companies have.
Q Have you ever performed a Failure Mode Evaluation Analysis for any type of mesh product?
A No, reviewed them.

Q Have you ever done an FMEA for any type of SUI product?
A I've only reviewed them, because they're the company documents that I learned to review at the FDA.
Q You're not an expert on how mesh performs in the body, are you?
A Yes, I am, in terms of what -- in terms it being a FDA reviewer, medical officer, you have to look at the effects of mesh, and one of the things would be shrinkage, contraction, infection, the porosity in terms of the migration of certain cells through the pores. So yes, I've looked at issues for that for mesh for the FDA --
Q You're not --
A -- and degradation, and then your double-sided meshes which would have a side that -- yes, so I've had to do that for FDA.
Q You're not an expert in the design process for pelvic mesh, are you?
A Not in the design process. I had to review, but not design.
Q Or any type of product -- SUI product.
A The design process -- I mean, I've had to look at all the -- I had to look at clinical studies for the

manufacturer. I don't know about -- I mean, I've looked at clinical studies for radiofrequency trying to show them to be safe and effective, get clearance from the FDA. So I don't know what --
Q But you're not an expert in the design process of any SUI product.
A The original design, that's correct.
Q Okay. You've never invented a medical product, have you?
A Well, I helped develop a medical product. I don't have a patent, in terms of a product that was to be implanted.
Q Do you have any expertise in designing or developing a medical product?
A Sure.
Q Other than from a regulatory standpoint?
A Well, no, no, as a consultant and working with a manufacturer to bring a new product to the market, I have to -- you participate with people who were creating the device, the how do you select materials, what standards do you use, what kind of information would you tell the FDA. So yeah, I've done that.
Q Well, let's talk about when you were at the FDA. You were there from '91 to '95, is that right?

A Yes, sir.
Q What, 20 years ago?
A Yes, sir.
Q Did you have a computer when you worked with FDA?
A Yes, sir, we did. I learned how to use WordPerfect; the FDA taught me how. It was a really crappy computer.
Q What kind of computer did you have?
A It was -- I don't remember what kind it was, but it was -- it was not good. But yeah, they sent me to computer classes to use it on, but you didn't have access to the internet. At that point in time, FDA reviewers weren't allowed to use the internet.
Q Did you or anyone that you worked with at the FDA have a laptop?
A Sure. There were laptops, but you had to buy your own laptop.
Q Did you or anyone you worked with at the FDA have a cell phone?
A No, there weren't cell phones back then. I don't think there were cell phones. No, I don't remember cell phones.
Q You're not here as a representative of FDA,

are you?
A That's correct. The cell phones -- actually, there were cell phones at that time. You weren't given a cell phone by the FDA. Is that what you're talking about?
Q No, I'm just asking -- I'm asking if you or anyone of your colleagues at FDA carried around a cell; phone.
A Yeah, in those days cell phones existed, because we had safety issues and health risk assessments that I sat in, because that --
Q I'm not asking if they existed. Move to strike as nonresponsive.
I'm asking if you or any of your colleagues at FDA carried around a cell phone, yes or no.
A I don't recall.
Q Okay.
A I don't recall. But I knew that they existed.
Q You worked in the Office of Health Affairs?
A Originally, the first two years with the Office of Health Affairs, yes, at CDRH.
Q Do you know, would that be the OHA?
A Yes, sir.
Q Do you know if it's still an office within the

FDA, as today?
A No, it was disbanded by Dr. Kessler and Dr. Burlington in 1993, and the few medical officers that were in it were supposed to go to pre-market issues, ODE. So I got transferred from that to ODE, Office of Device Evaluation. So I know it doesn't exist.
Q When you were working with FDA, you never had final authority to approve a device, did you?
A I think you mean final sign-off in terms of the letter? That's correct.
Q Correct.
A That is a chain of command that -- that is correct. I didn't sign -- did I have the authority to approve and deny? Yes, but not the final signoff.
Q And you never had responsibility for approving a drug label, did you?
A A drug label?
Q Um-hum, or a medical device label, final authority.
A I did as a clinician. If I didn't approve it, it wasn't going to get approved, but I didn't sign the letter. I agree, I did not sign the final letter. That's an administrative point of view.

Q Has FDA ever asked your opinion about labeling since you left in 1995?
A Yes, they have. They had me go as an expert on their panel about device labeling.
Q And when was that?
A 1997. They were trying to have an advisory panel to discuss ways of improving medical device labeling to make it more consistent, like drug labeling.
Q And is 1997 the last time?
A Yes, sir.
Q When you worked with the FDA, did you work with any type of mesh products?
A I don't recall, because mesh products -- I had a lot of surgical products I don't recall. I mean --
Q You don't recall being involved with any type of SUI products at FDA?
A I don't recall because I was also the medical officer for the urological and I also supported the OB-GYN, so I'm not sure, and occasionally I would consult for plastic surgery. So I don't know if that would cover all the places where they would come.
Q At FDA, you were never involved with any type of pelvic floor repair products, were you?
A I don't believe I was.

Q At FDA, you were never involved with Prolene.
A That's not true.
Q Okay.
A I actually had to go look at the NDA for Prolene for suture issues, because it was a transitional device, so I have looked at the NDA through the 510(k)'s. So I was involved --
Q For what reason?
A Oh, wait, I was involved with mesh being used for vascular grafts. So I did have to get involved with mesh, because -- it was mesh and other things.
Q But I'm talking about any type of mesh for SUI products. You've not been involved at FDA with any type of mesh used for SUI products, is that correct?
A That's correct, because they actually came on the market after I left, pretty much.
Q Why did you look at the NDA for Prolene?
A There were issues on suture, and so you had to go back to the NDA. I don't recall why, but I remember having to look at the Prolene NDA, which was over in CDER and going through it, and since I've been involved in litigation stuff, too, I've looked at suture and Prolene, so.... But it began at the FDA.
Q Okay. At FDA, did you ever work with J&J or

Ethicon?
A Yes.
Q Okay, on what?
A They were -- they have a lot of medical devices, and I also was involved with them after I left FDA, but in terms of, one of the issues was I think a product called Interceed that I was called in to as a chief medical officer to sit in a meeting that the company was selling a product with claims that weren't accepted to the FDA. So I had to work, trying to bring Interceed under -- in compliance with the requirements of the Act.
Q Would -- could -- but when you were working at FDA, you never worked with J&J or Ethicon regarding any mesh product, correct?
A Well, that's an abdominal adhesion product that's similar, but it's not --
Q I'm talking about a mesh product for SUI.
A Well, that's different. No, I wasn't involved in -- Johnson & Johnson, and then I was involved with Johnson & Johnson when I left FDA, I worked with them as a consultant.
Q When, with Johnson & Johnson?
A Yes, sir.

Q When?
A That would have been -- it's on my CV. That would have been -- I don't remember the years. It was early after I left FDA, Johnson & Johnson came and found me, because I had been involved in an issue, a device, kind of a device/drug issue, and so they asked me to write a letter to the internal -- to an internal medicine journal about my involvement as an FDA medical officer looking at their product, and they also had me write an article on the workup of preservatives in terms of drugs and devices, and then I taught at their national sales meeting one year. I have a clock from Johnson & Johnson saying thank you for my help. So yes, I did work for Johnson & Johnson.
Q You didn't consult with Johnson & Johnson about any mesh product, did you?
A Not for surgical mesh product, that's correct.
Q At FDA, you were never responsible for post-marketing surveillance of a medical device?
A Well, no, I was involved with post-market. That was with the OHA.
Q With a medical device.
A All medical devices, in terms of looking at the accuracy of warnings, instructions for use. I was

actually on a post-market surveillance, or -- the head of post-market surveillance for anesthesia products.
So yeah, that was what I did in OHA was post-market and all, and I would report to the Office of Compliance. I think that's where Tim Hulatowski was, in Office of Compliance. I was their medical support, because at that time they didn't have MDs.
Q When was the first time you'd ever heard of TVT Secur?
A TVT Secur, I really hadn't heard about TVT Secur until I was asked to be involved with TVT Secur. I had been involved with TVT and TVT-O in terms of all the other products, and I was aware of the clearance of it, I believe, in the '95 period, TVT, and so --
Q You were contacted -- strike that.
A In August, I believe.
Q In August of 2014.
A Correct, about TVT Secur. I may have focused on the others.
Q Have you ever seen a TVT Secur device?
A Now I have, in terms of the pictures. I haven't physically held one.
Q Do you understand the procedure for implanting a TVT Secur device?

A I don't think anybody does, but --
Q Let me ask you this: Do you agree that you do not have the requisite education, training and experience to implant a TVT device, a TVT Secur device?
A I would agree with that. I would agree with that for the entire -- I don't have -- to physically implant it in a patient, I would not even attempt it. And so I agree that I would not even attempt it, and that's not my role, and that -- FDA people don't have that training, either.
Q Do you know the difference between polypropylene and Prolene?
A Well, polypropylene is the material that Prolene mesh is made out of. It's a polypropylene mesh that can vary in terms of -- well, polypropylene, yeah, that's the answer.
Prolene can be a suture, and resin -- it's a resin. Polypropylene is a resin that's used to make whatever they need in terms of suture or mesh or what's ever made up of; it's called Prolene, and the trade name is Prolene, at Ethicon.
Q My question to you, though, is: Do you know the difference between polypropylene and Prolene?
A Yes, Prolene is --

Q What is the difference?
A Prolene is the trade name. Polypropylene is the type of resin that's used to make whatever product is going to be named Prolene.
Q Do you know -- what do you know about the manufacturing process Ethicon uses to make Prolene?
A Well, it's usually a mesh extrusion, polypropylene resin extrusion process, which you have of the extruder make fibers, and then you use the fiber to weave what you need to do in terms of your mesh.
So that's it basically, and then once you've made your fibers to your diameter and you've woven it the way it's supposed to, then you have to clean it, you have to sterilize it, and you put it in your kit.
Q And you know that mesh is made of knitted filaments of Prolene sutures, don't you?
A Yes.
Q We can agree to that.
A Yeah. It's thread, you can think of it as thread, and every mesh has its own design in terms of the way it's woven, in terms of the pores and -- yes, and it's multi-filament, I believe, in terms of the mesh.
Q I know we've talked about your opinions about

design defect, but do you have any manufacturing defect opinions?
A You know, manufacturing -- let me clarify what I think you mean. Manufacturing would, like a lot, did I look at Ms. Garcia's lot and look and see if there was an particular issue with her lot in terms of the quality assurance? No, I did not look at that.
So I don't have any specific manufacturing defect issues about the line, but I've not been asked to look at all the good manufacturing practices about specific lots.
Q Has any of your work at FDA or since then involved polypropylene or Prolene, with the exception of the hernia, the stuff that we talked about earlier?
A Yeah, I mean, AMS uses polypropylene in terms of their Sparc mesh. So I've looked at the Sparc mesh and the evolution of how that mesh comes out. So yeah, I've done that, and Kugel, like we said, and then I've looked at Bard's. I once did a case with C.R. Bard and Marlex mesh. So I've looked at polypropylene mesh.
Q Have you ever performed any type of study on the biocompatibility of polypropylene or Prolene?
A I haven't done any studies. I've looked at toxicology data in terms of the inflammatory response

that you get from different types of mesh, looking at -- and I've looked at more than just Prolene. I've looked at the soft meshes, light meshes, heavy meshes, ultra-light, all those different variations in terms of your weight and the type of biocompatibility responses you get for, like, hernia. I didn't do the hernia issues, but the hernia meshes. So I've looked at that, in terms of animal toxicology.
Q You've never participated in any clinical trials regarding polypropylene, have you?
A No.
Q Or done any clinical research on polypropylene?
A No.
Q Or you've never seen any degraded polypropylene?
A No, I've seen that in my world of going through meshes, I've seen degraded, but I've not -- I've not been -- made a study of degraded mesh.
Q Right, but have you ever seen degraded polypropylene under a microscope?
A I've seen -- I've seen slides of it, I mean, pictures. I haven't put one under the -- I have four microscopes, but I haven't put that under my microscope.

Q Have you ever done any type of independent testing or analysis or any root cause analysis to determine if Prolene is defective?
A No.
Q Let's talk about Ms. Garcia for a minute. You didn't review her medical records.
MR. LUNDQUIST: Object to form.
THE WITNESS: I did review Dr. Walss' testimony, and I do have --
MR. HUTCHINSON: Move to strike as nonresponsive.
Q I'm talking about medical records.
A Right, and I have her progress reports and medical records in one of my folders here, so that --
Q Oh, I'm sorry.
A So you would have that.
Q Have you spoken to any of her doctors?
A No.
Q Do you have any idea what information Dr. Walss relied on when he was consulting with Ms. Garcia?
A Based his testimony, yes.
Q Outside of what's in his testimony?
A No.

Q Do you know whether Dr. Garcia (sic) relied on the IFU?
A He read the IFU, so -- I have the IFU -- so yes, he did read it.
Q Do you have any idea of what training from Ethicon Dr. Walss may have received about the TVT Secur?
A All he says is that he went to a course. We don't know who presented it. He said there were other people, other devices being presented, and sales reps were there. We don't have a specific course. He said that he did have the sales rep come and watch him do several cases and say that he had -- he was doing it the way he was supposed to do it.
So that's in terms of his training. Then he's used the TVT and the TVT-O. That's all I can see from his depo in terms of the Secur.
Q And I'm sorry, I think you said Dr. Walss was using it the way he was supposed to?
A That's what he was told by the representative from Ethicon who watched him do a couple cases.
Q Do you have any idea of what potential risks of TVT Secur that Ms. Garcia's doctor was aware of?
A He was aware of the surgical risks of the procedure. He was aware that there could be a rare risk

for erosion and that it would be transitory. He testified to -- a lot about that, and -- but he did not know that it was more than rare, and so -- we know that that's, in terms of his informed consent, he didn't use that in the informed consent because he did not think that it was something that was actually going to occur, and that it was transitory, it wasn't permanent. And he wasn't aware of having to remove it -- the frequency for failure and the removal --
Q Do you know -- I'm sorry.
A -- and the risk for dyspareunia. He wasn't aware of that, too. I'm trying to remember what else he said he wasn't aware of.
Q Do you know whether Ms. Garcia saw the patient brochure?
A She did not. I don't believe she was specifically asked at her deposition, but she did not reference having seen one.
Q Have you ever spoken with any doctor who has implanted a TVT Secur device?
A No, sir.
Q Have you ever talked with any doctor about the IFU for a TVT Secur device?
A I haven't specifically spoken to him. I have

Dr. Miklos' report and I have Walss --
Q Well, what about any mesh product?
A Have I spoken to doctors who implanted mesh?
Q Yes, about the IFUs for any mesh product.
A No. I've seen a lot of IFUs for mesh products. I've not spoken to doctors specifically about them.
Q Did you do any type of study or survey of doctors to determine what risks associated with SUI surgery they're aware of?
A No.
Q Do you have any study or survey of doctors to determine what risks from the TVT Secur product that they appreciate from the IFU?
A We have Dr. Miklos, and Doctor --
Q Other than the plaintiff's expert.
A -- we have Dr. Walss, and he's relevant to Ms. Garcia, and so he wasn't -- he goes on about the things that he wasn't aware of, in terms of the IFU.
Q But no study or survey of doctors, correct, that you've done?
A That I've done, no, I haven't done a study.
Q You've never drafted a label or IFU for a mesh device, have you?

MR. LUNDQUIST: Form.
THE WITNESS: I don't recall, because the FDA doesn't draft the labels, they look at the labels, but I don't recall if any of the PMAs actually had a --
BY MR. HUTCHINSON:
Q Or any types of SUI device.
A For an SUI device, I did work with a manufacturer that I did help draft the labels as a consultant for that, and I evaluated their data.
Q And what manufacturer was that?
A I think it's INSURx, I-N-S-U-R-X, and it was that they had gotten rejected by the FDA on their clinical data and I was brought in to go over the clinical data to kind of reorganize it, reevaluate and then it got cleared.
Q And that was with -- I'm sorry, INSURx?
A I believe that's what the name was, I-N-S-U-R-X. I was brought in by another consulting firm, Weisbrod, I think -- not Weisbrod, Weisberg. It was a consulting firm in Washington, D.C. I don't remember their name. Anyway, they needed someone who could go through the clinical data.
Q You've never drafted patient brochure for a mesh device, have you?

A For a mesh device, no, that is correct.
Q Yes, ma'am, or for an SUI device?
A Well, I worked on their device, but --
Q I'm talking about a patient brochure.
A Yeah, they had a patient brochure.
Q Have you ever consulted with the FDA about an SUI mesh device?
A Consulted for -- specifically, no. Well, I did consult for this company that went into the FDA and got cleared. I didn't go to the meetings with the FDA, that I recall.
Q And what product was this INSURx trying to bring to market?
A It was a radiofrequency device that's used for treating the woman's vagina, urethra, so that you would decrease SUI. It was just an alternative treatment, sort of like they use Botox when you're thickening the tissue.
Q But it didn't have any mesh in it.
A No mesh, no mesh.
Q You've never sat on a FDA warnings or label committee, have you?
A I don't know what that would be. I mean, have I sat on committees where you talk about warnings or

labels for the FDA? It's not a committee. Because, see, drug does have that, the CDRH doesn't have that. Yes, I've sat on safety issues in the sessions about labels and warnings.
Q Have you ever designed any label readability studies?
Label readability studies, for the court reporter.
A Readability. I actually consulted for the division in CDRH that was doing that when they were trying to develop home health products, and so I was the medical input as to their readability. I didn't design the study.
Q You've never talked with FDA about the regulatory history about the TVT Secur, have you?
A No.
Q Do you intend to offer what the -- the actual verbiage, do you intend to offer opinions about what the actual verbiage of the IFU should say?
A Yeah, I could do that. And which IFU? They only that had one IFU for the Secur, so yeah, I can talk about the verbiage, what's missing.
Q That's what I want to ask you about. I'm going to hand up what I'll mark....

What's the next exhibit?
(Whereupon, Exhibits 6 and 7 were marked for identification.)
BY MR. HUTCHINSON:
Q Dr. Parisian, I'm handing you what I'm marking as Exhibit 6 and Exhibit 7 to your deposition.
A Okay.
Q And Exhibit 6 is the IFU and Exhibit 7 is the patient brochure. Does that look right?
A No, this is the later one. This is 2011. Her surgery was 2012. I looked at 2008. Yes, I think it is, okay.
Q Let's look at Exhibit 6 now.
A I'm also pulling up Dr. Miklos, because he also talked about what he thought --
Q Well, I don't want to talk about Dr. Miklos. I want to talk about your opinion. So let's look at Exhibit 6.
A Okay, but I can pull it up.
Q Did you review Exhibit 6 in forming your opinions?
A Yes, sir.
Q What criticisms do you have about the IFU that was marked as Exhibit 6?

A Okay. Is this the order that it really is in? Yeah. One of the criticisms is that the information about risk and benefits and all should be up front. They're showing the procedure, so like, if you're a physician, you're going to be -- more likely it's going to be the procedure, to look at the procedure, not look at the IFU.

Q Right.

A So right away, that downplays the IFU information, which --

Q Okay, what else?

A -- which increases the need for the company to communicate through its sales reps or through Dear Doctor letters, is typically the design of that, and what you --

Q So I'll tell you what, Dr. Parisian. Help me make a list, please. I want to know what all criticisms you have of the IFU marked as Exhibit 6.

Number one, I have information regarding risk and benefits should be up front, correct?

A Right, it's on page 10.

Q And what's your second criticism?

A Okay, let me tell you. Again, the positioning. They have the description --

Q I'm sorry?

A The positioning of it.

Q The positioning of what?

A Of the label. They have it --

Q Of what on the label?

A I'm going to tell you.

Q Okay.

A They have, under Description, they have this long description of the polypropylene mesh, its filaments. Doctors aren't going to read that. It's got to be up front.

Q What page are you on?

A I'm on page 10. You're putting stuff that a physician who's implanting this is not going to care about.

Q All right. So let me ask you this, and make sure we're clear: That what you suggest is that the wording on page 10 under Description should be up front, correct?

A No.

Q All right, help me out.

A I'm saying that the way this is written about the -- in terms of physicians --

Q No, I'm not asking about physicians, I'm

asking about what your opinion is, about what the -- what your criticisms are about the IFU.

A And I'm telling you.

Q Okay.

A The placement of it, the --

Q The placement of the description --

A No, no.

Q -- on page 10?

A No, no, no. The placement of the important information for the IFU is actually -- and we're up to page 10, and you've got this long description that no surgeon is going to sit there and want to read --

Q Okay, so --

A -- about polypropylene mesh and all this stuff, and --

Q So you believe that the information on page 10 should be moved to the beginning of the IFU; is that what your testimony is?

A No.

MR. LUNDQUIST: Form.

BY MR. HUTCHINSON:

Q Then where should it be moved?

A That's what -- I'm looking at the label and I'm going to tell you what's going to be moved. In

terms of -- you've already the lost the physician. He's not going to read any of this stuff.

Q Move to strike as nonresponsive. I'm asking you, where should --

A I'm going to tell you what needs to be moved, okay?

Q -- it be moved?

A Hold on. All this is surgical stuff. When you see the contraindications, warnings and precautions, you should have that up front. It's now on page 20, so we're 10 pages back from where anything begins --

Q Move strike as nonresponsive. I'm asking you, where --

A I'm telling you.

Q -- the information on page 10 should be moved in the IFU?

A It should be moved to after -- it should be shortened, for one thing. The description should be just that little part up there, the first part, and then you should have --

Q I'm not asking how it should be shortened or how it should be lengthened. I'm asking where it should be moved.

A It should be front, the first page.

Q Okay, so you're telling me that the information on page 10 should be moved to page 1, correct?
A Yes.
Q Okay.
A And it should be -- because the device -- it's describing what the device is, and then the next thing that should come is the indication for use.
Q All right, so the criticisms that I have is, number one, the information regarding risk and benefits should be up front instead of page 10; the second criticism I have is the placement of important information on page 10 should be moved to page 1.
What other criticisms, if any, do you have about the IFU?
A Well, the device description is so long, it's not telling the doctor what he needs to know. He needs to know what's up in that first description. He doesn't need to know all this stuff about the sandwich-bonded thermal -- doctors don't care about that.
Q All right. So, Doctor --
A Okay, then you have the --
Q -- Dr. Parisian, stay with me. So you're testifying that the information on page 10 under

Description is too long, correct?
A Yes.
Q And Dr. Parisian --
MR. LUNDQUIST: Sorry, she was about to write on the exhibit. I was just making sure.
BY MR. HUTCHINSON:
Q And you're testifying also that the information about the sandwich sections -- I'm sorry -- the information about the sandwich that ends the section of the mesh should not be included in that, correct?
A Not there, the way --
Q I'm sorry, is that correct?
A Not -- yes.
Q All right.
A Because when you design a label, you want to have the information up front, so that the most important information is available to a physician. Chances are that your marketing and your sales rep is going to have to convey this information, but if you're going to make an effective IFU, you put the most important information up front. I don't think there's a physician around who would care about how this is knitted and -- that doesn't make any sense to them. They think it's a cleared device. They have here the

description of what the device should have in it. Then you have the indications for use, which is the important thing, what is it intended for. Then you go into the instructions for use --
Q All right, well, Dr. Parisian, stick with me. So we're talking about your criticisms, and I have three so far. I'm sorry, I have four.
I have information regarding risk and benefits should be up front instead of page 10. The second one is, important information on page 10 should be moved to page 1. Third is, too long device description on page 10; and the fourth criticism I have is that we shouldn't discuss the sandwich -- the section of the end of the mesh, on page 10.
Anything else?
A Yeah. All those --
Q What else?
A All those pictures, 1 through 10, should be under the Instructions For Use.
Q Okay, I'm sorry, you're saying the pictures on pages, actually, 2 --
A Right.
Q -- through 8 should be somewhere else, is that correct?

A Yeah, they have no business being up front. They should be under Instructions For Use, because they're relevant to the different positions, the U-position and the H-position. Without a picture, it's really bad instructions.
Q You do understand that I've handed you what was marked as Exhibit 6 to be the Instructions For Use of TVT Secur.
A I know, but they're not designed correctly. Now I see why people talk about cookbooks.
Q So the pictures are not designed right?
A No, the pictures are in the wrong place.
Q Pictures wrong place, okay.
A They should be under the Instructions For Use, where you're talking about the specific procedure, the U-procedure, the hammock procedure. You have to have pictures in the right section.
Q Do you have any other criticisms --
A Yeah, yeah.
Q -- of the IFU?
A Okay, so we have -- we started out with the Description and the Indication For Use. Then we would have, after that we would have, before you started into the Instructions For Use, you would start with the

contraindications, because a physician needs to know up front what's the contraindications. That should be up in the first --

Q I'm sorry, contraindications?

A Yeah.

Q Should be where?

A Right up after the Indications For Use.

Q Contraindications should be where, after...?

A Indications For Use.

Q On what page?

A They should be probably be out on page 1 or 2.

Q Contraindications should be on page 1, is that correct?

A Well, it should follow the Indications For Use.

Q I'm asking you, where should contraindications be located?

A Well, you can't know what page, because we've moved the Description, we've shortened it. So we've taken --

Q Contraindications should be up front?

A Yeah --

Q Okay.

A -- after the Indications For Use, you should

have the contraindications.

Q And where is contraindications now?

A It's on page 20.

Q Okay. So it should be up front rather than on page 20, correct?

A Yeah, in the contraindications.

Q Do you have any other criticism?

A Well, yeah, I do. Just let me look at the contraindications... (Deponent reading document.)

That contraindication comes from surgical mesh Prolene.

Q I'm not asking where that contraindication came from. I'm asking you about your criticisms.

A Okay, I'll tell you what my contraindications --

Q I'm not talking about your contraindications. I'm talking about your criticisms --

A I'm going to tell you.

Q -- of the IFU, in Exhibit 6.

A Okay, the company says to the FDA that you can only use this product in certain selected patients. So if there's a patient that should not be appropriate for this product, say, weight, if the woman is too obese, it could be in the contraindications, it could be in the

warnings and precautions, but who this product shouldn't be used for, anyone with an allergy to polypropylene, there are patients with that, they should not also be in here.

Q So your opinion is that the contraindications are poorly worded, correct?

A Well, no, they're not complete.

Q Not complete.

A If the company knows of people that should not be implanted, that would be where you would put this information. And they're implying to the FDA, and to -- in the discussion of Australia, that they know that there are patients that this product is good for and not.

Q What should the contraindications have included that they don't include already?

A Well, the 8 centimeters mesh was chosen because it would fit most patients. So if it doesn't fit most patients -- this isn't a two-size device, it's a one-single-size device -- that would be in the contraindications.

Q Okay.

A If a woman that's too obese, or -- what woman is contraindicated, what --

Q What other criticisms do you have about the IFU?

A Well, we're still -- so the contraindication if a person has an allergy to polypropylene, there are people that do, then that would be contraindicated in that patient --

Q Okay.

A -- and --

Q So my question to you is, what other criticisms of the IFU do you have?

MR. LUNDQUIST: She hasn't finished answering your question, I don't think, on contraindications.

Have you?

THE WITNESS: Right. So if the contraindications --

MR. HUTCHINSON: No, she testified that the contraindications are incomplete.

THE WITNESS: All right, and that they should be addressed.

Okay, the Warnings and Precautions is now what we're going through. At this time --

BY MR. HUTCHINSON:

Q My question is: What are your criticisms about the Warnings and Precautions? Is it the placement

or is it the verbiage, or language?
A Well, all -- we're talking about, okay, the placement. This should be up front, on page 1 or 2, not page 20.
Q Okay.
A Okay, let me look at the warnings. Okay, they have a statement under Warnings and Precautions,
"Users should be familiar with surgical technique for urethral suspension and should be adequately trained in the Gynecare TVT Secur system before using."
I've criticized that they don't have a certification, so how would a physician out there adequately train to use it? All they're saying is that you have to know how to use -- do urethral surgery. Dr. Walss did a lot of urethral surgery.
Q Move to strike as nonresponsive.
A Well --
Q We're not talking about Dr. Walss.
A No --
MR. LUNDQUIST: She's answering your question.
BY MR. HUTCHINSON:
Q So my question is: What other criticisms do you have about the IFU?

A It defines -- it should define what would be someone who's adequately trained. Would it be someone who would go to a course? Would it be -- you know, and so their marketing should be consistent with that, that those people who were adequately trained, by definition here, then should use this product. That would be a warning.
Q What else? What other criticisms do you have?
A The second, that it should be used with care to minimize the chance of damage to large vessels, nerves, bladder and bowels --
Q I'm sorry, is this the language?
A No, no, this is -- I'm just showing you where I am.
Q I know, but you're reading a document.
A Right.
Q My question is: What criticism do you have about the IFU?
A Well --
Q And I'm making a list. So what is the next one on our list?
A We're moving to the next one, where they're saying that it is important to pay attention to the specific patient's anatomy while inserting the device.

Q Okay, so is that --
A That's a --
Q Is that a criticism you have about the language under the warnings?
A Yeah.
Q Okay.
A That's a real stupid statement.
Q Anything else?
A I mean, to a physician, that means nothing, I mean. And also, you don't say that the device, unlike the other devices, is sharp. So it does have a tendency to cut.
Q So other than a criticism of language in the warnings, do you have any other criticisms of the IFU?
A No, I'm still going, looking at -- we're looking at Warnings and Precautions.
Q Well, you've already criticized the language, I get that, but other than the criticisms of the language and the warnings, do you have any other criticism of the IFU for TVT Secur?
A I think they tell them, for the hammock position, that bladder injury is unlikely, but --
Q Where are you?
A I'm moving down the warnings, under the

"hammock" position.
Q Okay, and that goes to the language, correct?
A Well, no, no. It's -- this is a warning, okay? And so for the hammock position, the hammock position is the most commonly used position and also the one that's getting reported with bladder perforation.
Q What's your criticism about that, the language?
A Well, no, it doesn't give the post-market information about the bladder perforation rate.
Q Okay.
A Because it's one thing to say that it's unlikely to occur with this technique, but bladder perforation is actually being reported, I think, in some documents, at 19 percent. So that information underplays the potential risk to a physician on the hammock position.
Q All right.
A And then the hammock position, as we saw also, if the device isn't put near the pubic bone, you may actually hit blood vessels, which was another thing that was there. So if you're going to talk about the risk of the hammock position, you need to say those.
Q Do you have any other criticisms --

A Yes.
Q -- about the IFU?
A Now, they're saying, "Ensure that the tape is placed with -- "
Q I'm asking you, do you have any criticisms about the IFU?
A Yes.
Q Okay.
A I'm telling you what.
Q What's the next criticism?
A Based on the information they have, this is not a good IFU. They also --
Q What's your criticism?
A I'm going tell you, "Ensure the tape is placed with -- "
Q You're just reading from a document.
A No, I'm --
MR. LUNDQUIST: She's giving the basis for her --
THE WITNESS: I'm trying to tell you where I am, why it's wrong.
BY MR. HUTCHINSON:
Q I meant, what's your criticism?
A You're telling a physician, under Warnings and

Precautions, that there should be no tension placed under the mid-urethra.
Q And you believe that's wrong.
A I believe that's wrong and inaccurate, in terms of their internal documents, when they say tensioning is very important in terms of this device, and so this is not an adequate warning.
I mean, these are warnings. Warnings are like, red light, yellow light, important information, and this is not -- this is not telling them that tensioning is very important to the success of this procedure; and you see that through all their documents, and that information's not there, and --
Q What other criticisms do you have, Dr. Parisian, of the IFU?
A The other is that there is nothing here about the learning curve. All the documents internally are discussing the long learning curve --
Q And so let me ask you this: Is your opinion that there should be something in the IFU that says there's a long learning curve?
A Yeah.
Q Okay.
A Because they're talking --

Q And -- hold on just a minute, stick with me. What other opinions do you have, or criticisms, rather, about the IFU?
A Okay, I'm talking -- these are warnings, and so the learning curve should actually go up where they're talking about, the physician should be aware of the surgical technique and adequate training. Okay, then, you would put the learning curve in there. These are warnings. Warnings are supposed to be, before you use this, Doctor, you need to know this.
Q Stick with me. So what other criticisms do you have?
A The next statement, "Acceptable surgical practice should be followed," that's not a warning. Doctors know that.
Q And so that shouldn't be in there, correct?
A "...should be followed -- "
Q Is that correct?
A Let me look at it. As well -- I mean, yeah, that's not a warning, because doctors would think of that just in terms of surgical stuff. What should be there is the potential for these things to be contaminated and difficult to remove. That's a better warning. Here, this is just telling a doctor he needs

to know how to do surgery technique. That's not a warning.
Q Which bullet point are you?
A I'm on the first one on page 21.
Q Okay. All right, the acceptable surgical practice. All right, any other criticisms?
A Well, the next one, do not perform this if you think the surgical site may be infected. You're talking about the urethra and the woman's vagina, which is contaminated --
Q So you don't like the bullet point -- you don't like the language in bullet number 2 on page 21, correct?
A Correct.
Q All right, any other criticisms?
A Okay, so they do mention removal --
Q Doctor --
A No, I'm continuing on that --
Q Do you have any other criticisms of the IFU?
A Yes, yes.
Q Okay. What are they?
A Okay, where they're talking about the surgical site, they're saying that it must only be with the understanding that subsequent infection may require its

removal. Actually, the tape has been removed for many reasons. So this would be where you would highlight the risk of infection, the potential removal, a need for additional surgical procedures, and it could be difficult to remove and you actually may never be able to treat the infection.

So you have, the risk of infection could be a permanent issue, you may not be able to remove the surgical mesh, and it may be something that could cause problems forever. So that doesn't convey that.

Q All right. Do you have any other criticisms? I'm making a list about what -- hold it just a minute, Dr. Parisian. Listen to my question. I'm making a list and I'm up to 15 now criticisms that you have for the IFU. Does that sound about right so far?

A Yeah, I'm going through the IFU with you --

Q Okay.

A -- we're all the way through, you --

Q I know, but does that sound right so far? You have at least 15 criticisms of the IFU so far?

A Yeah.

Q Okay.

A It's not -- it's got a good IFU.

Q Okay, if you could continue.

A All right.

Q What's your next criticism of the IFU?

A I don't know why they put the pregnancy there.

Q Is that a criticism?

A You could actually put a pregnancy as a one single line. Yeah, this is --

Q All right. My question is, is that a criticism?

A Yeah.

Q Okay, so we're up to 16?

A Yeah.

Q Okay.

A But see, in terms of warnings, you're supposed to put the most important things first. It's not likely that this is going to be used on a pregnant woman, but --

Q What other criticisms do you have about the IFU?

A I'll go on. There's again, pregnancy, women. You could have just put pregnancy off by itself as a separate population, because it's not going to be what a physician who's potentially going to be doing this is thinking about. You could have had a special population and had pregnancy under that, considerations for

pregnancy. That would -- let's see...

Okay, the next is just a routine warning for surgical procedures.

Q Is that a criticism you have?

A Yeah.

Q Okay, so is that 17 criticisms?

A This would just be --

Q Doctor -- Dr. Parisian --

A I don't know if would be or not, but you would use --

Q Okay. Dr. Parisian --

A Yes.

Q Are we up to 17 criticisms you have for the IFU?

MR. LUNDQUIST: Object to form.

THE WITNESS: I don't know. You're keeping track. I wouldn't argue with you, but --

BY MR. HUTCHINSON:

Q Well, if I've counted to 17 criticisms you have of the IFU, would you have any reason to dispute that?

A No, sir.

Q Okay.

A The other is that --

Q What's number 18?

A Number 18 would be that the postoperative should be under the Instructions For Use, not under the Warnings and Precautions, because that would be postoperative information that you would tell your patient about, not to jog. So it doesn't need to be in the Warning and Precautions, it needs to be under the Instructions For Use and the postoperative course.

Q Okay.

A It's just in the wrong place.

Q What's number 19?

A Okay, and the same with, "Patient should be instructed to contact surgeon," that should be under postoperative care and instructions for use.

Q All right, what's number 20? What's number 20, Dr. Parisian?

A I'm looking. The next talks about de novo destrusor stability.

Q And what's wrong with that?

A There's no information as to how frequent, and yet they're trending it in their own post-market information. So how frequently does that occur for this device, in terms of a meaningful warning for a physician?

Q What's number 21?
A Twenty-one, we'll leave that --
Q What's your 21st criticism of the IFU?
A Well, in terms of the IFU, in terms of Warnings and Precautions, the information that needs to be in there that's not in there, because I've gone through the information that is, should be the failure rate. What is the likelihood of the failure rate, based on tensioning, inadequate tensioning --
Q Is that -- I'm sorry.
A That's not in the warnings at all.
Q Is that your 21st criticism?
A Yes, sir.
Q Okay. What would be the -- do you have any other criticisms of the IFU?
A I don't think the number really applies, because we're talking about a redesign of a label that's inadequate.
Q What is your next criticism of the IFU, Dr. Parisian?
A Let me think about it. Let me think about it. Okay, you need to include the failure rate that they've --
Q I'm sorry, the failure rate?

A Yes.
Q Doctor, Dr. Parisian, you're talking real fast on me. Including the failure rate, would that be the 22nd criticism you have of the IFU?
A Yeah, there's no information in here about the high failure rate that's being seen in the post-market information.
Q Do you have any other criticisms of the IFU?
A Let me think. I'm thinking. Actually, I think that I would have divided this label differently in terms Warnings and Precautions, because medically -- drugs had combined warnings and precautions in 2006, but not medical devices.
So there should be a hierarchy of warnings versus precautions, because warnings would be your higher risk information, like, do not use an anticoagulation therapy, that first one, that's a warning, whereas a precaution -- putting them together doesn't give a doctor....
So the way they've categorized -- you can make it 20 whatever-it-is -- the warnings and the precautions should be separated, because warnings are of higher risk to a physician implanting the device and it needs to be highlighted. It wasn't combined in medical devices, it

was combined in drugs.
Q Dr. Parisian, your -- what is your -- your 24th criticism was to divide the label differently. What is your 25th criticism, though --
MR. LUNDQUIST: Form.
BY MR. HUTCHINSON:
Q -- of the IFU?
A Okay, but I wanted to make it clear for you, I'm talking about -- we just went through Warnings and Precautions. I'm not going to go back through the list.
Q I understand that. I understand that. That's why I'm keeping the list. So --
A Some are higher for warnings, they're appropriate warnings, and some are lower risks, things that are something -- a precaution, and that would be something that needs to be divided from Warnings and Precautions.
Q All right. What is your 25th criticism of the IFU?
A Let me go through. There's nothing about -- okay, Adverse Reactions, it should be -- Adverse Reactions is what they're calling it; they want to call it that, or complication. And let's look at that.
Q All right. Dr. Parisian, before you -- I'm

still making my list. So what's your 26th criticism of the IFU?
A Well, I'm looking at the Adverse Reaction section.
Q Can you list the 26th criticism? Otherwise, we'll move on.
A Yeah, sure I can.
Q Okay.
A I mean, looking at it right away, one of the issues is the use of the word "transitory" or "local irritation" -- "transitory local irritation." The words --
Q And that's a criticism?
A Oh, it's a big criticism.
Q Okay. What's your next criticism?
A Well, no, why is it my criticism?
Q No, I'm sorry --
A It should be --
Q Dr. Parisian, listen to my question. Stick with me, okay? What's your next -- what's your 27th criticism of the IFU?
A Okay, but let's go back to 26.
Q No, I'm taking this deposition, Doctor.
MR. LUNDQUIST: Doctor, it's all right, if he

doesn't --
BY MR. HUTCHINSON:
Q I'm going to ask you a question. What's your 27th criticism of the IFU?
MR. LUNDQUIST: If he doesn't want the basis for it, he's welcome to ask what the criticisms are.
THE WITNESS: And that isn't what --
MR. LUNDQUIST: That's fine.
MR. HUTCHINSON: I'm totally entitled to know what her criticisms are.
MR. LUNDQUIST: You are.
BY MR. HUTCHINSON:
Q What's your 27th criticism?
A Well, my 27th is that instead of the word "transitory," it should be "permanent."
Q Okay, what's your -- do you have any other criticisms of the IFU?
A And it should be -- yes.
Q Okay. What's the next one?
A The Adverse Reactions is totally inadequate. There's nothing about need for revision surgery, and there's nothing about the difficulty removing of the mesh. There's nothing about the potential risk for infection, chronic pain, dyspareunia, change in your

vagina in terms of scarring. None of that information is in here. So the Adverse Reaction is totally inadequate --
Q Okay.
A -- in terms of the information.
Q Do you have any other criticisms of the IFU?
A Let me --
Q And your 28th criticism was the Adverse Reactions language, correct?
A It's still inadequate.
Q I'm sorry, is that correct?
A Yes, it's totally inadequate.
Q Do you have any other criticism of the IFU?
MR. LUNDQUIST: Just for clarification, are you talking about just the inadequacy or what she thinks should be in here, or are you asking about --
MR. HUTCHINSON: I'm talking about her criticisms.
MR. LUNDQUIST: Fair.
THE WITNESS: Oh, because I'm trying to tell you what should be in there.
BY MR. HUTCHINSON:
Q Have we discussed all of your criticisms of the IFU?

A Yeah, it's -- and I can summarize. It's --
MR. LUNDQUIST: You don't need to summarize, that's okay. Thank you. If you've gone through them, Dr. Parisian, I think --
THE WITNESS: So you're going to ask me what needs to be in it?
BY MR. HUTCHINSON:
Q No, I'm going to ask you to summarize for us what your criticisms are for the IFU.
A Okay. The design of the document is not correct. The information for the physician that he needs to know about choosing this device is not up front.
There's too much discussion of the device. You can put that later in the labeling, to describe the device.
The Instructions For Use, the surgical procedure needs to be later in there. They need to tie the precautions that go with the Instructions For Use with pictures. You need to have pictures, so that the physician would know what the potential procedure is. You can't have pictures not together.
Adverse Events is deficient. It doesn't talk about the permanent nature of the complications, in

terms of risk versus benefit.
So the sum is that it's an inadequate label in terms of risk versus benefit information for a physician choosing to use this product versus another product.
It also doesn't talk about the post-marketing history, the learning curve, and what a physician needs to do to be able to use this device safely on a patient.
And what kind of information oftentimes the label will have information for consulting for your patients, counseling your patients, there's nothing in here for a physician about information you give to a patient.
Q What should the label say?
A Okay, the label should say that -- just what I said, in terms of the summary. It needs to put the risk information, the warnings and precautions divided separately up front, with the contraindications under the device description with the intended use, the indication for use.
It needs to convey if there are any patients that are not appropriate; what kind of training a physician has. The difficulty with tensioning needs to be in here, and in implanting. It also needs to, as post-market data is obtained, the high failure rate at

12 weeks, in terms of this device: Do you want to use this product versus another product?

It also needs to have a list of the adverse events, complications that can occur, that they can be permanent, that it can be difficult to remove a mesh, that infections cannot be treated, perhaps; that removal of the mesh -- you cannot remove all of the mesh and you may still have infection.

It also doesn't discuss anything about nerve injury, that people will have chronic pain. It doesn't -- it implies that the issues of complications are going to be temporary and transient. Those are not the right words, and the company internally was talking that was the wrong term to use.

So, you know, it just doesn't convey the risk versus benefit information in an adequate prescription label for a 21 C.F.R. 801.109.

Q Have we discussed all the language you believe that should be in the IFU?

MR. LUNDQUIST: Object to form.

THE WITNESS: That's what I think.

BY MR. HUTCHINSON:

Q Dr. Parisian?

A I think that, in terms of, I am not a

clinician, and so as an FDA reviewer looking at the warnings and looking at what the medical literature has covered, those are my opinions.

We also have to take Dr. Miklos, because he actually can talk --

Q I'm not talking about Dr. Miklos.

MR. LUNDQUIST: She's answering your question. She's answering your question.

MR. HUTCHINSON: Move to strike as nonresponsive.

MR. LUNDQUIST: Doctor, you can continue your answer.

THE WITNESS: I'm going to refer to him in order to talk about the training, because he was a preceptor and he would know about the adequacy for the IFU training, because I haven't focused on that.

BY MR. HUTCHINSON:

Q Okay, and have we talked about all of your opinions regarding language that should be in the IFU?

A All the -- all the language? Because -- did we talk about the language? I mean, we talked about it in the beginning, the dyspareunia, product -- is that in your...?

Q I'm asking you. I'm asking you, have we

talked about all the language that you believe should be in the IFU?

A The -- yeah, I think also it needs to have an adverse reaction that failure has been found at 12 weeks, in terms of the medical literature --

Q Okay, anything else?

A -- and their own data.

Q Anything else?

A That their long-term performance hasn't been determined by the company.

Q Anything else? Dr. Parisian, anything else?

A I'm thinking, I'm thinking. I think also, in terms of the fixation, the fixation, there's no information about the success of fixation with the Ethisorb.

Q I'm talking about the language.

A Right, no, the right --

Q So tell me, have we discussed everything?

A There's this whole discussion of the freeze in the design, but there's nothing about that this has never been used for this indication before, in terms of the Dura Patch that they're using.

Q Anything else?

A That information needs to be there to tell the

physician that the fixation hasn't been determined, and there's no long-term data about that. So difficulty removing, training. What else? I think that's about it.

Q Dr. Parisian, are you aware of any IFU on the market that has everything that you have suggested in it, and in the order in which you've suggested it?

A Actually, a lot of the information was suggested by the FDA in 2008 --

Q Move to strike as nonresponsive. I'm not asking about the FDA.

A Well, there's different components of it.

Q My question -- my question to you is, are you aware of any IFU on the market that has all the information in it and in the order you think it should be in it, yes or no?

A I don't know. I mean, I don't think so, because this is specifically looking at the documents for TVT Secur. The documents for TVT-O and the documents for TVT and other product would be different, but in terms of the information, there's -- some other of the labels may actually have some of that.

Q Dr. Parisian, did Ethicon do anything correct when they drafted this IFU for TVT Secur, anything that

they did well?
A Let me look. In terms of this IFU, no.
Q Okay, and Dr. Parisian, you'll know that the FDA did review this IFU before it cleared TVT Secur, correct?
A It was included in the 510(k) package, but the FDA reviewed it for the intended use. They didn't review it, they don't approve it.
Q Well, my question to you is: You do know that the FDA looked at the IFU that we've talked about before it cleared TVT Secur, correct?
MR. LUNDQUIST: Objection.
THE WITNESS: No, we know that it was in the FDA's submission, the 510(k). I will agree with that.
BY MR. HUTCHINSON:
Q Okay.
A We don't really have any comments. We have Dr. Herrera saying he doesn't know how you could put this device in. So FDA didn't approve that. That's an IFU.
Q I'm not talking about approving, I'm talking about clearing.
A Well, you're --
Q FDA -- just stick with me. FDA cleared TVT

Secur, correct?
A They did, but not that label.
Q And FDA had this label at their office when they cleared TVT Secur, correct?
A It was with the 510(k) --
Q Is that correct?
A Yes, it was with the 510(k) submission --
Q And that clearing --
A -- and Herrera's comment is that --
Q And that clearing -- just a minute. By clearing the TVT Secur, FDA gave Ethicon the green light to market this, correct?
A Only to market it, but not with that IFU.
Q Right, and --
A FDA doesn't review the IFU. That's up to Ethicon, and the only thing the FDA reviewed in the 510(k) was the intended use, and the submission and the representation that this device was exactly the same as TVT and TVT-O, and some of that information is from TVT and TVT-O.
And so the FDA only reviews labeling for the intended use. They didn't -- that's not cleared by the FDA or approved by the FDA, and you can say it all you want, but it's not.

Q Did FDA -- strike that. Did Ethicon violate any federal regulations with the IFU that was marked as Exhibit 6?
A Yes, 21 U.S.C. 352(a) --
Q Any others?
A Well, I'm explaining it. I'm answering your question.
MR. LUNDQUIST: Let her finish.
THE WITNESS: 21 U.S.C. 352(a)(f)(1), (f)(2), in terms of mis-branding; 21 C.F.R. 801.109, adequate prescription label; 21 C.F.R. 1.21, failure to reveal material facts. Twenty-one -- those would be the main ones in terms of the labeling, adequate instructions for use. Yes, sir.
BY MR. HUTCHINSON:
Q And this --
A So those are violated. Those are not consistent with the information that -- and I'm not going to say violated. Those are not in compliance. If I was an FDA regulatory expert, with the requirements for an adequate label, based on information that the company has, especially in 2010, because we're looking at labels that began when it was first cleared, but once it was marketed, and by 2010, that label is not an

adequate label for Ms. Garcia.
Q Let's look at Exhibit number 7. That's the patient brochure that you have in front of you, correct?
MR. LUNDQUIST: You're going to launch into a whole new -- as far as the brochure, so is now a good --
MR. HUTCHINSON: Patient brochure?
MR. LUNDQUIST: Yeah, I figure you probably have a good deal of questions on that. Can we kind of take a --
MR. HUTCHINSON: I really don't think I'm going to do --
MR. LUNDQUIST: Maybe a 30-minute lunch break, unless you just want to --
MR. HUTCHINSON: Why don't we -- so you want to take a break now?
MR. LUNDQUIST: I mean, we've been going for about three and half hours. So just 30 minutes, back at, let's call it, back 10 to one?
BY MR. HUTCHINSON:
Q Well, let me ask you this: Do you have a lot of opinions about the patient brochure that we haven't already talked about?
A Yeah.
MR. HUTCHINSON: Let me -- all right, why

don't we take a -- plaintiff's counsel, you want to take a --

MR. LUNDQUIST: Thirty.

MR. HUTCHINSON: -- 30-minute lunch, is that right?

MR. LUNDQUIST: Let's call it that.

MR. HUTCHINSON: Okay. All right, fair enough.

(Luncheon recess taken from 12:24 p.m. to 1:10 p.m.)

BY MR. HUTCHINSON:

Q We ready?

A Yes.

Q Okay. We're back on the record after having lunch and ready to go. Dr. Parisian --

A Yes.

Q -- the label in this case is the IFU, correct?

A Yes, well -- the label, yes, as opposed to labeling.

Q Correct, but we're talking -- when we talk about the label, you and I are talking about the same thing in this case?

A In this case, yes.

Q And I think, before we took a break, you gave us 28 to 30 reasons or so about why you believe the IFU

was defectively designed, correct?

MR. LUNDQUIST: Object.

THE WITNESS: And then I summarized, tried to say why, because it's not the points as much as the way it's laid out.

BY MR. HUTCHINSON:

Q And the label is part of the product?

A Yes.

Q And you can't separate product from the label; meaning the two of them go hand-to-hand, right?

A Well, in what sense? In terms of a regulatory sense, you can. If you're talking about a 510(k) clearance, they're different. Because the only thing that's really reviewed is the indications for use in terms of 510(k) clearance, and then you get a nice clearance letter saying it's up to you, manufacturer, to ensure your labeling, which would be your IFU, is adequate.

Q Well, certainly Ethicon couldn't sell the TVT Secur device without an IFU, could they?

A No, they have to indicate what the intended use is.

Q So if the label is defectively designed, it's your opinion that the product's defectively designed,

correct?

A It's misbranded. I mean, I've had a lot of other opinions about defective design, but we're talking about the IFU, and the label is misbranded, it's inadequate, particularly by the time Ms. Garcia has her surgery.

Q Does that mean that the product was defectively designed?

A Just based on the labeling? In terms of the training for the physician, yeah, we discussed that in terms of the design in the very beginning.

Q Okay. Did you determine -- did you do any tests to determine if the product was defectively designed?

A Yeah, I think I have -- well, I haven't done any physical tests.

Q Okay.

A I've looked at documents about it, and --

Q Okay.

A -- and reports.

Q Are you relying on -- I know you've looked at documents, but are you relying on any peer-reviewed publications or scientific literature as the basis of your opinion that the product is defectively designed?

A I would look at the Cochran report. The Cochran report went and came up looking at all randomized controlled studies that had been done and said, very nicely, that it was not an adequate product to use and that it would have been withdrawn from the market.

Q Can your theory the TVT Secur product is defectively designed, can that theory be tested?

A From a regulatory point of view? Sure. In terms of the methodology that I'd use is exactly the same methodology I would have used at the FDA to make that same determination: Is this an adequate device? Are the instructions adequate?

So that that methodology can be tested, and then the post-marketing reports actually substantiates that it wasn't adequately designed --

Q Have you done --

A -- in their own internal discussions. So based on the medical literature, their own company reports, their own testimony, their own documents, and -- it is inadequately designed. It did not meet -- by "inadequately designed," I mean it's not meeting its users' needs, in terms of what the design requirements are, and that would be under 21 C.F.R. 820.

Q Has your theory been tested?
A Has my theory...? You mean my process or methodology?
Q No, I'm talking about your opinion that the TVT Secur device is defectively designed. Has that theory been tested, yes or no?
A I don't understand the question.
Q Have you done any tests to determine if the TVT Secur device is defectively designed?
A No, I have not.
Q Are you aware --
A Can I clarify? You mean physical tests? Have I taken it into a laboratory and done physical tests? No.
Q Well, have you done any types of tests to determine if the product is defectively designed?
A Other than looking at the internal documents and company reports and the post-marketing, I mean, it's the company documents that have actually been what's defectively designed and as my basis for that opinion, and the medical literature.
Q Is that a no?
A I don't think I'm understanding your question.
Q Okay. Have you done any test to determine if

the TVT Secur device is defectively designed?
MR. LUNDQUIST: Object.
THE WITNESS: Where I put it in the laboratory and tested it? I haven't done any testing like that.
BY MR. HUTCHINSON:
Q I'm talking about any tests.
MR. LUNDQUIST: Object to form.
THE WITNESS: I've done what a regulatory expert would do in terms of looking at adequacy of design and what I would have done at FDA. I used the same kind of documents.
BY MR. HUTCHINSON:
Q But have you done any tests other than physical tests?
MR. LUNDQUIST: Object to form.
THE WITNESS: I haven't done any physical tests, but I've used the documents that a regulatory expert would rely on to come up with that opinion.
I'm not -- I don't -- are you trying to say, am I an engineer that would have done physical laboratory testing? No, I'm not, but the documents I've used are the same documents that I would have used at the FDA to say, is there an issue with this device; health risk assessment, in terms of a health risk

assessment.
BY MR. HUTCHINSON:
Q Has a safer design been manufactured?
A Well, in terms of Ms. Garcia --
MR. LUNDQUIST: Form.
THE WITNESS: -- we have the TVT-O. Since Dr. Walss has been familiar with that, he said that's what he would have used if he had known about the potential risks.
BY MR. HUTCHINSON:
Q Well, my question to you is: Do you believe that a safer design, other than a safer design than TVT -- strike that.
Do you believe that there is a safer design on the market compared to TVT Secur?
MR. LUNDQUIST: Form.
THE WITNESS: Yes.
BY MR. HUTCHINSON:
Q And what was that? What was that safer design?
A Based on the company documents, the medical literature, Dr. Miklos, it would be the TVT and the TVT-O. Now, I'm not saying they're safe, but I'm saying they're safer than the TVT Secur.

Q Are you relying on any controlled study to support your opinion that the TVT Secur caused injury to Ms. Garcia?
A A controlled study? Why would I rely on a controlled study? I'm relying on all the company documents and the information about the potential risks.
Q And that's all?
A And also we have Dr. Miklos, Dr. Walss, you know, those -- in terms of a health risk assessment, I'm relying on the totality of all those documents.
Q Right, but I'm asking you about a controlled study. Are you relying any controlled study, yes or no?
A Not one specific controlled study, no, sir.
Q What -- and I believe it's your testimony that the TVT or TVT-O, in your opinion, would be the proposed alternative safer design, is that right?
A Based on what Dr. Walss said, I would go with the TVT-O.
Q Okay.
A Or no treatment at all.
Q And are you aware of any study comparing the current IFU that we have talked about as Exhibit 6 to the proposed IFU that you claim is safer?
A The current study -- I know we have

Dr. Miklos, it's not -- from his clinical practice as a physician and knowledgeable at the --

Q I'm not asking about Dr. Miklos, I'm asking about studies.

A Well, there hasn't been a study of my proposed label tested because it's based on documents that I've reviewed. If the company wanted to do that, they could do that, but I haven't seen that the company has done such a study.

Q The IFU that you propose has never been cleared by the FDA, has it?

A It wouldn't need to be. The company could have done it immediately.

Q Is that a no?

A That's correct, and by 2010, which is the time period we're talking about, the company had not updated their label. So they would have the IFU that we discussed, and I don't know that -- and FDA doesn't have to clear a 510(k)'s label. The manufacturer can update it immediately.

Q In fact, the IFU that you propose has never been submitted to the FDA, has it?

A That's correct.

Q Okay, not even by you.

A Why would it be, by me? That's correct.

Q And it's fair to say that no mesh manufacturer has ever included an IFU like the one you believe is safe, with their product?

MR. LUNDQUIST: Form.

THE WITNESS: I've seen various mesh manufacturers' labels. They have components of the information that I have, at various different times. Their labels have been changing since the FDA's public Health Announcement 2008. So their labels are evolving.

So much of that information isn't included in the labels. I think there's a discussion in 2009, when the company's comparing TVT's label using the word "transitory" versus AMS label, where the transitory doesn't occur. So there are components of those statements --

BY MR. HUTCHINSON:

Q I'm not talking about components, I'm talking about an IFU exactly like the one that you had proposed to be safer.

MR. LUNDQUIST: Object to form.

THE WITNESS: "Exactly" is the word, yes, but --

// //

BY MR. HUTCHINSON:

Q Exactly. Am I correct?

A In terms of -- I --

MR. LUNDQUIST: Form.

THE WITNESS: That's correct, I mean, because nobody would have written the entire label -- I didn't write a label. I told you what was deficient in your label and what should be there. So there isn't a label that I've even created, other than to tell you what my opinions are in terms of what's missing from the label.

BY MR. HUTCHINSON:

Q Is -- so I guess it's fair to say that no one in the world has ever marketed a product with an IFU -- with the IFU like the one you believe is safe, correct?

MR. LUNDQUIST: Object to form.

THE WITNESS: Well, the label --

BY MR. HUTCHINSON:

Q I'm just asking for a yes or no. Then you can explain your answer.

MR. LUNDQUIST: Form.

THE WITNESS: Yes, because we're talking about a TVT Secur label, not every label in every one in the world, and the company could have used that label at any time, and making a label that's very specific for their

post-marketing information, which had never been included in their initial label. They had one label that came out and was never updated with any post-market safety information.

BY MR. HUTCHINSON:

Q Is there a mesh manufacturer of a mini-sling on the market that has an IFU that you believe is better than Ethicon's?

A There are labels for other manufacturers that have been updated over time that are better than you would compare to the 2011 label -- what date was that label that you showed me? Oh, that was the very first label.

Yeah, the other manufacturers that I've seen labels that are better than TVT's label, one would be AMS, one would be Boston Scientific. Their labels have different components, they're not perfect labels, but they're more robust than the Ethicon label.

Q Let's talk about the IFU that you propose and compare it to the current IFU for TVT Secur, okay?

A Well, you asked me my opinions on the -- I didn't propose and draft a label.

Q Okay, and in fact, that's something that you're not doing in this case, correct?

A I wasn't asked to do that. You asked me specifically what are my opinions on the label, and I gave you my opinions on the label. I didn't draft a better label, other than to tell you how I would rearrange the information. So there isn't a drafted label by me other than the opinions.

Q Okay, and so that's something you've not done is, you've not drafted a better label than the one for TVT Secur, correct?

A I haven't physically drafted -- that's what I wanted to be clear. I haven't physically drafted a label. I've told you what's deficient in terms of inadequate information. There are consultants like me that could draft a label, but I haven't done that.

Q Since you haven't talked with Dr. Walss, then you don't know if the IFU that you proposed would have made any difference in how he selected the product, do you?

MR. LUNDQUIST: Object to form.

THE WITNESS: Based on his deposition, I do.

BY MR. HUTCHINSON:

Q Okay.

A His deposition said it did. He repeatedly said if he had known that, he wouldn't have -- what was

in the IFU, he wouldn't have used the product, he would have used the TVT-O, which he knew how to use and had used. So he repeatedly said that.

Do you want examples or just, is that enough for you?

Q Since you haven't spoken with Dr. Walss, do you have any idea if the IFU that you propose would have made any difference in the way he performed a risk/benefit analysis?

A Based on his testimony, the information that I was adding would have, according to him, have changed his use of the product. I haven't physically spoken to him, but knowing what he said was important to him in terms of the information and use of the product, yes, I think it would have, but that would be up to him to answer that.

Q And do you know if the IFU that you proposed would have made any difference in the way he discussed the procedure with Ms. Garcia?

A The way I did propose it, yes, because I was adding post-market information, which he didn't have, and it could have been sent to him in a Dear Doctor letter, it could have been told him by the sales rep. So there's other communications besides the IFU.

Q My question is: Since you haven't spoken with Dr. Walss, do you know if the IFU that you proposed would have any made difference in the way he discussed the procedure with Ms. Garcia?

MR. LUNDQUIST: Object to form.

THE WITNESS: I only can rely on his testimony, and he said it would have.

BY MR. HUTCHINSON:

Q So it's your opinion that a TVT-O would be a safer design?

A It's relative. It's safer than a TVT Secur.

Q And TVT-O is a multi-sling -- multi-incision sling, correct?

A Right.

Q And a TVT Secur is a one-incision sling.

A Single-incision, yes.

Q So it's your opinion that a two-incision sling is better than a one-incision sling?

A No, it's not my opinion. My opinion is that for a physician to know how to be able to use a device, it makes it a better device. Dr. Walss is familiar with a TVT-O, and he was not familiar and was not able to be familiar with the tensioning issues because the company didn't instruct him on it for the TVT-S. So you're

always better off having a doctor using a product that he's aware how to use rather than one he's not.

Q Dr. Parisian, you've never designed an alternative design, like the one you believe is safer, have you?

A For what?

Q For stress urinary incontinence.

A An alternative design of what?

Q An alternative design of the TVT Secur.

A Oh, so you're saying for another device.

Q Yes.

A No, I've not designed a device, but Dr. Walss, which is the important part, said he would have used the TVT-O, which has, based on the company's documents, a lower risk of recurrence of SUI and other problems. It has risks, but lower risks than TVT Secur.

Q I want to hand you what we'll mark as Exhibit 8 to your deposition.

A Sure.

(Whereupon, Exhibit 8 was marked for identification.)

BY MR. HUTCHINSON:

Q I believe you've seen this document before, correct?

A Yes, General Controls of Medical Devices.
Q In fact, this is on the reliance list.
A Yes, sir.
Q And when you worked with FDA, you knew what general controls for medical devices were, didn't you?
A Sure.
Q General Controls provide the FDA with means of regulating devices to ensure safety and effectiveness, correct? I'm in the introduction part.
A Where are you reading?
Q The introduction part.
A General Controls...
Q General Controls provide the FDA with means of regulating devices to ensure safety and effectiveness?
A Right, Congress required that the FDA would come out with General Manufacturing Practices, GMP.
Q And you agree with that statement I just read, correct?
A That was the purpose of the --
Q I understand.
A Yes.
Q I'm not asking about the purpose. Just stick me, and we'll get through this.
A Yes.

Q You agree with that, and the next sentence says, "General Controls and the amendments apply to all medical devices." You agree with that correct?
A Yes, sir.
Q And including Ethicon's?
A All devices, all --
Q Including the TVT Secur that Ms. Garcia received, correct?
A Yes.
Q Those standards apply to Ethicon and the product, correct?
A All medical devices sold in the United States, yes.
Q I'm sorry, is that correct?
A Yes. I think I have two. Did somebody else need one?
Q If you look -- if you turn with me to page 2 --
A Um-hum.
Q -- under Key Points, it says,
"General Controls are the basic authorities of the Medical Device Amendments that provide FDA with the means of regulating devices to ensure safety and effectiveness."

You agree with that, right?
A Yes.
Q And the FDA's General Controls, they address safety now, right?
MR. LUNDQUIST: Object to form.
THE WITNESS: Well, the purpose is to attempt to address safety. They -- the FDA doesn't specify General Controls per se for each manufacturer.
BY MR. HUTCHINSON:
Q But these standards address safety, correct?
A Right, under good manufacturing practices.
Q And these controls, or standards, are mandatory for Ethicon to follow, correct?
A Yes.
(Whereupon, Exhibit 9 was marked for identification.)
BY MR. HUTCHINSON:
Q Okay, and if you look at what I'll hand you as Exhibit 8 -- I'm sorry -- Exhibit 9 to your deposition, Dr. Parisian?
A Um-hum, yes, sir. This the newest one.
Q Guidance for Industry and Food and Drug Administration Staff, correct?
A Well, this is the newest one. There's been a

series of them before that. This is the 2014 --
Q But we'd want to look at the newest one, wouldn't we?
MR. LUNDQUIST: Form.
THE WITNESS: Depends what your question is. Because we're talking about back in -- I have no -- I have no need to quibble about this. I'm just saying, this is the newest one.
BY MR. HUTCHINSON:
Q Well, let's look at Exhibit 9. You relied on this for reaching your opinions, correct?
A Yes, sir.
Q And when you worked at FDA, you relied on guidance documents like this to educate you on certain topics?
A Oh, I didn't rely on this, I already knew this. I had been trained, everything in here. This is basically for manufacturers to try to facilitate their awareness of when they need to put in a 510(k). So there's -- there was no change in the regulations.
Q Well, so here, if we look at this document, we have FDA giving guidance to both industry and its staff about the 510(k) process, right?
A Yes, new staff, basically, but the regulations

hadn't been changed.
Q Do you disagree with anything the FDA was telling the medical community and its own staff in this document?
A No, I'm not. I'm just saying I knew about this long before this guidance.
So do you have a question?
Q Let's turn to page 3.
A Okay. Got it.
Q It's the last sentence. It says, "Because...," the last sentence on page 3. Do you see that?
A Yes, sir.
Q Okay. It says,
"Because devices are classified according to the level of regulatory control necessary to provide a reasonable assurance of safety and effectiveness, classification of a new device through the 510(k) process requires FDA to determine the issues of safety and effectiveness presented by the new device and the regulatory controls necessary to address those."
Did I read that correctly?

A Yes, sir.
Q And did FDA get it wrong here, or is it correct?
A No, it's right.
Q So basically you're saying, or -- basically, what you would agree with, as we kind of sum it up, is the 510(k) review provides reasonable assurance of safety and effectiveness.
MR. LUNDQUIST: Object to form.
THE WITNESS: No, no, the term "reasonable" is used with PMA. It determines the issues of safety and effectiveness, based on the predicate device. The predicate device, unlike a PMA, is used for clearance of the -- supportive clearance of the 510(k) for the device substantially equivalent. So yeah, that's correct.
BY MR. HUTCHINSON:
Q Okay.
A And if you're found substantially equivalent to a predicate device, that controls.
Q I know that. We'll get to that in a minute, but if the device has been 510(k) cleared, the FDA has found reasonable assurance of safety and effectiveness, fair enough?
MR. LUNDQUIST: Form.

THE WITNESS: No, you're adding -- where do you see "reasonable"?
BY MR. HUTCHINSON:
Q On page 3.
A Page 3, okay. Reasonably assured of safety -- to provide, okay, but that's not "reasonable," because they use "reasonable" in the PMA regs, and --
Q Just, if you could stay with me. If a device has been cleared in the 510(k) process, you'll agree that FDA has found there's a reasonable assurance of safety and effectiveness, correct?
MR. LUNDQUIST: Object form.
THE WITNESS: Yes, based on the predicate.
BY MR. HUTCHINSON:
Q Thank you, and the 510(k), that relates to clearance of the device, not approval.
A That's right.
Q And that's something that would be relevant in this case if we wanted to have a full picture of the regulatory background of TVT Secur.
MR. LUNDQUIST: Object to form.
THE WITNESS: Of course it's relevant.
BY MR. HUTCHINSON:
Q Okay. It would also explain the history, the

regulatory history of the product, wouldn't it?
A Yes. Do you want to discuss that?
Q We will in a minute.
A Okay. I want to understand the question, here.
Q If you'll turn -- well, let's switch gears for a minute, and let's talk about -- well, while we're on here, while we're talking about FDA 510(k) clearance, the 510(k) also relates to the safety of the device, correct?
MR. LUNDQUIST: Form.
THE WITNESS: Based on the predicate device, but only to -- the device has not been marketed, so based on the safety of the prior device.
BY MR. HUTCHINSON:
Q If we have a -- strike that. Let's talk about Prolene sutures for a minute. You're familiar with Prolene suture, I believe you've already testified to, correct?
A Yes, sir.
Q And I'll hand you what we'll mark as Exhibit 10 to your deposition.
(Discussion off the record.)
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(Whereupon, Exhibit 10 was marked for identification.)

MR. HUTCHINSON: Will? Pay attention. Make sure that's on the record.

THE WITNESS: All right.

BY MR. HUTCHINSON:

Q Now, you've seen this document before, haven't you?

A Yes, sir.

Q And you will agree that TVT Secur's mesh is made of these knitted filaments that we talked earlier about, of Prolene suture, right?

A Well, it's the same polypropylene.

Q It's the Prolene suture. It's knitted filaments together.

A Right.

Q And if you look at this document, this is -- it says NDA 16-374, is that right?

A Yes, sir.

Q And that's the number that was assigned to the NDA for Prolene sutures.

A Yes.

Q And FDA approved the NDA for Prolene sutures on April 16, 1969, correct?

A Yes, sir.

Q And it's been in use since.

A Yes, sir.

Q And these were approved by FDA as a drug.

A Under the drug regulations, because the medical device regulations hadn't been made yet.

Q And that approval includes labeling, correct?

A Yes, that would include the labeling.

Q Right, so the FDA concluded that the Prolene sutures were safe and effective for intended use.

A As a suture, yes, sir.

Q And FDA approval of NDA means there's a finding by the FDA that that drug is safe and effective for use in the human body, as labeled?

MR. LUNDQUIST: Object to form.

THE WITNESS: Yes, it was an NDA approved product.

BY MR. HUTCHINSON:

Q And if somebody wanted a complete history about -- a complete picture about the regulatory history, this would be the starting point, won't it?

A This is where I started, yes, sir.

Q Okay, and over the years, there has been -- there have been supplements to NDA 16-374, correct?

A Right, until it was transitioned over to CDRH.

Q And do you know how many supplements there have been?

A No.

Q And one --

A I don't recall how many supplements there have been.

Q Did you look?

A At one time I did.

Q You don't know now?

A I don't know, sitting here today.

Q And every time the FDA approves a supplement, that's confirmation that Prolene suture is safe and effective as labeled, correct?

MR. LUNDQUIST: Object to form.

THE WITNESS: For that specific indication. They don't go back and re-look at everything. It's only on a specific indication.

BY MR. HUTCHINSON:

Q Now, let's talk about before 1976. FDA regulated medical devices just like they did drugs.

A No.

Q Before 1976?

A No. Let me explain.

Q Okay.

A They had certain drugs -- certain devices that the FDA was concerned about safety issues, and so the FDA chose to apply the drug regulations to certain devices that would be referred to as the "transitional" devices.

So they were actually required to have an NDA approval, and the requirements were comparable to what was required at that time for approval, because those have been evolving, too, in terms -- this was pre the 70's, when FDA would have required clinical trials.

Q Right.

A They didn't do that here, but --

Q Right. Well, but one of the medical devices that FDA regulated just like drugs was the Prolene sutures, correct?

A Yes, sir.

Q And --

A Just as a suture, not as a mesh.

Q And if we look at -- let me make sure I understand something.

A Sure.

Q A pre-amendment device is one that was sold before the Medical Device Act of 1976, correct?

A For a medical device, yes, sir.
Q Okay.
A So we call it pre-amendment, but not all pre-amendment devices were regulated as drugs. This was a transitional pre-amendment device that actually the NDA came over as a PMA approval when they got regulated, devices.
Q And you'll agree that pre-amendment devices, with a few very specific exceptions, were grandfathered as safe and effective, correct?
A Yes.
Q Okay. In fact, that's what you wrote in your book, "FDA Inside and Out."
A That's right, but that's not specifically -- you need to look at the section on transitional devices, because this was already NDA-approved. So it is safe and effective as a Prolene suture. It was transitioned to having a PMA approval when it moved over to CDRH.
So it's a little higher standard than what you're reading there for the pre-amendment device, because not all of them have any kind of clinical trials.
Q Right, but the Prolene sutures, that was a pre-amendment device.

A It was a transitional device, technically, but it was pre-amendment.
Q And the Prolene mesh was a pre-amendment device, correct?
A The surgical mesh was a pre-amendment device, but it came if from Usher, I think, before 1976. So mesh was pre-amendment. Prolene was NDA-approved. So the material, the resin, was NDA-approved.
Q Well, Prolene mesh was grandfathered in as safe and effective.
A Based on that it was a surgical mesh which was pre-amendment. So the mesh -- yes, we're not -- I mean, it's a cleared device. I'm not talking....
Q Right.
A But technically, surgical mesh was a pre-amendment device. Prolene was an approved material as an NDA.
Q And FDA has never done anything to change the fact that Prolene mesh was grandfathered in as safe and effective, have they?
A No.
Q Okay.
A It's based on the history. I don't think FDA really could do anything.

Q After 1976 amendments, Prolene sutures became a PMA Class III device, right?
A Well, they're --
Q I'm sorry, is that right?
A Yes, they're a PMA-approved device, so therefore, they're a Class III, but then they were reclassified into 510(k) Class II.
Q And Class III devices require FDA review and approval.
A Yes.
Q Okay, and in fact, Prolene sutures remained a Class III device until the FDA down-classified it in 1990.
A Right. In fact, Ethicon wanted to keep it a Class III device. It was the rest of the industry which supported re-classification, and so FDA re-classified it.
Q And what does it mean when something is down-classified?
A It means that FDA -- in this particular case, they said that they reviewed the medical literature and they felt that there could be accurate, er -- adequate controls to ensure safety and efficacy with using general controls and special controls, rather than the

controls -- also special controls, of the -- that have to be developed in a PMA or NDA, so it could then, from then on, be cleared as a 510(k).
Q All right. Let's talk about, going back to Prolene mesh, though, that's a pre-1976 device?
A No, mesh, mesh in general. Surgical mesh was used in the Vietnam War and it was pre -- pre-amendment.
Q I'm talking about Prolene mesh, pre-1976 device, correct? We just talked about that.
A Prolene is, yes, but it's based on a product, the Prolene that actually had been NDA-approved.
Q And it's made of the knitted filaments, just like the Prolene suture.
A Well, no, it doesn't look like suture. That's where --
Q Okay, I'm not asking what it looked like. I'm asking about what it's made of.
A Yes, it's made of the same resin.
Q Correct, and it's made of the exact material previously approved by FDA as safe and effective, correct?
A The resin is, which is used for the suture.
Q And because it was a pre-1976 device, it was grandfathered in as safe and effective, as a Prolene

mesh.
MR. LUNDQUIST: Object.
THE WITNESS: All surgical meshes were. Even Marlex mesh was grandfathered in. So yeah, it was, but see, there's a difference in structure between a mesh and a suture. The material was approved --
BY MR. HUTCHINSON:
Q I understand.
A -- and surgical mesh was what the grandfathered device --
Q But stick with me. The original Prolene mesh was made of the exact material that FDA had already approved as safe and effective, correct?
A For a suture, yes, sir.
Q Okay, fine, and then ultimately, FDA classified surgical mesh, including Prolene mesh, as a Class II device.
A Yes.
Q You know that.
A Yes.
Q Okay, and that occurred in the 1990s, based upon your review?
A It was late 1980s, early 1990s, somewhere in there.

Q Okay, and FDA reached that decision after recommending, or -- after considering recommendations of three panels of experts, correct?
A You mean their classification panels. Yes, their standard classification panel. The panel recommended that surgical mesh should be cleared as a Class II device, and FDA did accept that.
Q And those panels held open meetings?
A I believe so. They're public, the information.
Q Did you go to any of those?
A No. I think it predated my time at the FDA.
Q I'm going to hand you what we'll mark as Exhibit 11 to your deposition. If you can put that 10 back there?
A Yes, sir. I got more than 10. Are you going to do the --
Q Just set it aside. We'll...
A Got it. Yeah, 1982.
(Whereupon, Exhibit 11 was marked for identification.)
BY MR. HUTCHINSON:
Q So you've seen this document before, correct?
A Yes, sir, talking about mesh.

Q And in fact, you relied on it in forming your opinions.
A At various times, yes, sir.
Q And if we look at page 17 -- well, first of all, this is a proposed rule classifying Prolene mesh as a Class II device, correct?
A Right, that's how that works. You have to come out with a proposed rule, first.
Q Okay, and look with me on page 17.
A Yes, sir.
Q It says,
"Summary for reasons for recommendation: The Panels recommend that surgical meshes be classified into class II (performance standards) because the Panels believe that the device has an established history of safe and effective use."
Did I read that correctly?
A Yes, sir.
Q Okay. Do you agree with that?
A Yes, knowing the history of what they were reviewing, because they're talking about going -- the original surgical mesh was actually for reinforcing soft tissue, bone, and it was used in trauma patients in

Vietnam, and it wasn't always permanently placed. It was transient. So yeah, I believe that there had been a history of surgical mesh use in the past.
Q Well, but let's be clear. You agree with the expert panels that the FDA employed in that the device has an established history of safe and effective use. That's something you agree with, correct?
A Based on the history --
Q I'm sorry, is that a yes?
A Yes. Knowing --
Q I'm sorry, is that a yes?
A Yes, knowing the documents they're reviewing, yes. It's not anything to do with surgical, for urological uses.
Q And FDA then classified Prolene mesh as a Class II device in the latter part of 1998 -- I'm sorry, 1988.
A Correct, and then they have performance standards, which FDA never issued. So there was an expectation that FDA was going to issue performance standards for different devices, and they didn't.
Q And it's been in use ever since, right?
A Yes.
Q Okay. So I want to hand you what we'll mark

as Exhibit 12 to your deposition, Dr. Parisian.
A Okay. Are we done with this?
Q Yeah, you can put it in that stack.
A Got it. Yes.
(Whereupon, Exhibit 12 was marked for identification.)
BY MR. HUTCHINSON:
Q And you've seen this, or -- this is the July of 1990 order down-classifying sutures, right?
A Yes, sir.
Q And this is a document that you relied on in forming some of your opinions?
A About the history of mesh, yes, sir.
Q Correct. And if you look at the first paragraph, it says, "FDA concludes...," are you with me?
A And this is in response to a petition by U.S. Surgical. U.S. Surgical wanted to -- Ethicon wasn't --
Q Look at the first paragraph.
A All right.
Q It says, "FDA concludes...," you see that?
A The first --
MR. OLIVEIRA: Second sentence.
THE WITNESS: Second sentence. Yes, sir, I see it. Um-hum, suture.

BY MR. HUTCHINSON:
Q Actually, turn to the last page for me. Robert Sheridan, he's on this letter on behalf of the FDA. You see that?
A He signed it on behalf of Office of Device Evaluation, so he --
Q And you worked for FDA.
A Yes, sir.
Q Did you ever work with Robert?
A Yes, sir.
Q Did you know him?
A You know, I never worked with him. He was at the center when I was there, and then he retired shortly after I was there, so....
Q Is he a competent individual?
A I don't know.
Q You don't know?
A Well, I know his background is totally different. He's an administrative person, no clinical background, but he was in management at the FDA.
Q If we look at page 12, ETH.MESH09634675. Do you see that?
A Okay. Page 12?
Q Correct.

A Where are you? Based on -- what paragraph? I'm on page 12.
Q Okay. The second from the bottom paragraph, it says, "In this matter...," do you see that?
A Um-hum.
Q It says,
"...significant publicly available information indicates that the existing nonabsorbable polypropylene surgical sutures are generally safe and effective."
Did I read that right?
A Yes, sir.
Q And do you agree with that statement?
A Yes, sir.
Q Okay, so let's just be clear that you agree, as an FDA expert in this case, that the polypropylene sutures were safe and effective, correct?
A Yes, sir.
Q And also, if you turn with me to page 7 of this document, bottom paragraph, and the last sentence there says,
"...and that the polymer's degradation proceeds slowly and is generally not considered clinically significant under most

circumstances of use."
Did I read that correctly?
A That's what it states, yes, sir.
Q And you agree with that, don't you?
A That that's what it states?
Q No, you're agreeing with that statement, correct?
A Let me look at the whole statement.
MR. LUNDQUIST: Object to form.
THE WITNESS: This was actually based on the time period, in terms of, there's been knowledge about suture, different things that cause sutures to oxidize and degrade since this time, but this is in 1990. So it reflects the information considered in 1990.
BY MR. HUTCHINSON:
Q Well, my question is: Do you agree with that statement?
A That it reflects 1990.
Q Do you agree that the degradation is clinically insignificant under most circumstances of use? You agree with that?
A They're talking about suture.
Q Right.
A So in terms of --

Q I understand. I understand. I'm asking if you agree with that.
MR. LUNDQUIST: Object to form.
THE WITNESS: For suture, yes.
BY MR. HUTCHINSON:
Q And let's be clear. The mesh is made up of the exact type of material that suture is, correct?
A That's not what they're talking about, though.
Q I'm not --
A They're talking only about suture.
Q Stick with me. Stick with me.
A But you can't generalize from here.
Q I understand. Move to strike as nonresponsive. Stick with me.
You will agree that the suture is made up of the exact -- I mean, the mesh is made up of the exact material as what the suture is made of, correct?
MR. LUNDQUIST: Form.
THE WITNESS: Yes, they're both polypropylene, but they're not the same. This is suture, which is a different area, surface area, than mesh. And it's a different indication, because people usually tend to use multiple sutures in a surgical site. So one suture may not be quite as important.

BY MR. HUTCHINSON:
Q Let's look at page 12, bottom paragraph, last sentence. Are you with me?
A Page 12, bottom paragraph. We're flipping through the -- okay, bottom paragraph, all right.
Q It says,
"...determination of comparable safety and effectiveness of future nonabsorbable polypropylene surgical suture and marketed sutures can be made in the context of a pre-market notification under Section 510(k)...."
Did I read that right?
A Well, it's -- yes, this is classified in a 510(k), for suture.
Q And that means that the FDA uses a 510(k) paradigm to determine comparable safety and effectiveness.
MR. LUNDQUIST: Form.
THE WITNESS: For suture, yes, sir.
BY MR. HUTCHINSON:
Q Okay, and it's fair to say that the mesh that Ms. Garcia received was made up of small sutures that FDA previously approved as safe and effective.

MR. LUNDQUIST: Form.
THE WITNESS: No, her mesh is not sutures.
BY MR. HUTCHINSON:
Q It's made of the exact same material that was previously approved by FDA as safe and effective, correct?
MR. LUNDQUIST: Form.
THE WITNESS: Polypropylene is approved and cleared. I've never said anything -- as a suture --
BY MR. HUTCHINSON:
Q I understand.
A -- but there's differences in risk between a mesh and a suture, and --
Q But my question -- stick with me. My question is: The mesh that Ms. Garcia received is made of the exact same material that FDA had already approved as safe and effective, correct?
MR. LUNDQUIST: Form.
THE WITNESS: So? I mean, that's --
BY MR. HUTCHINSON:
Q I'm sorry, just a yes or no, and then go on and explain your answer.
MR. LUNDQUIST: Form.
THE WITNESS: Yes, it's made of polypropylene,

but that's really irrelevant, because this is talking about suture, and this document is basically, so FDA is justifying why they're not going to come out with mandatory performance standards for sutures, because they were saying that they thought it was low risk, the suture material. So that's what this document is saying.
But yes, but just because things are made of the same material doesn't mean the risks are potentially the same in a human being.
BY MR. HUTCHINSON:
Q Dr. Parisian, you're familiar with the Safe Medical Device Act of 1990, correct?
A Yes.
Q And you'll agree that it added to the 510(k) application process a new section called Summary of Safety and Effectiveness?
A Yes, sir.
Q Okay, so the 510(k) process, at least in part, deals with safety, correct?
MR. LUNDQUIST: Object to form.
THE WITNESS: Yes, but the safety based on the predicates, not on the device itself, because it hasn't been marketed.

BY MR. HUTCHINSON:
Q Have you ever -- and by the way, let's talk about your book for a minute. You wrote a book called "FDA Inside and Out," is that correct?
A Yes, sir.
Q That was published about Fast Horse Press?
A Yes, which is my company.
Q You're the only owner of that company, aren't you?
A It doesn't even exist as a company, but yes, I was the only person -- my husband, I think, took the money for the books, and so -- but it doesn't even exist anymore.
Q I'm sorry, explain that to me. How can you be the owner of a company that doesn't exist?
A Well, it's not -- it's a doing business --
Q Just explain to me, please.
A From a legal point of view, it's a doing business under the name, but it's under my company, my corporation, Medical Device Assistance, which is now MD Assist, Inc. So it's now like a facet of that group.
Q Is this still the only book that Fast Horse Press has published?
A Yes, and we don't even sell them anymore. So

we don't sell them. I mean...
Q Who gets -- how many books did this -- did you sell of this FDA Inside and Out?
A Not that many. I mean, I think we originally had -- I don't know, probably less than a thousand, but we're not selling them anymore.
Q I'm sorry?
A Other people sell them. We've given books to other people to let them sell. So I don't know how many have been sold.
Q You don't sell this book anymore, fair enough?
A I don't, that's correct.
Q Okay, and why not?
A Because I don't have time to fool with it. Other people have been willing to sell it. The price we've allowed them to reduce it to whatever -- it was -- so I don't sell it. It's not like it was a money winner, it was never meant to.
Q Does Fast Horse Press still publish this book?
A No, it was a one-time publication.
Q So this book is not in circulation anymore, is that correct?
MR. LUNDQUIST: Form.
THE WITNESS: It is in circulation. There are

medical libraries that have it, and people have it. I don't know how many people have it. So it's in circulation. You can get it on Amazon but, you know, I don't know how many are out there.
BY MR. HUTCHINSON:
Q If I were to call Fast Horse Press, who would answer the telephone?
A Nobody, because I believe Fast Horse Press used to be in Front Royal, Virginia, so there is no Fast Horse Press.
Q Do you -- during your review of this case, did you review the 510(k) for modified Prolene mesh?
A I have reviewed -- you mean in terms of the surgical mesh for modified Prolene mesh? Yes, I've reviewed certain, like, Dynamesh, yes, there's mod- -- yes.
Q No, I'm talking about the 510(k), K962530, for modified Prolene mesh. Did you review that?
A At one time I did, yes, sir.
Q And that would be on your reliance list, correct?
A I don't know if it would be or not, because I've reviewed it for other things that I've reviewed the Prolene mesh.

Q Do you know what device was used as a predicate for modified Prolene mesh?
A Probably Prolene mesh.
Q And FDA -- based on your review, you know that FDA cleared modified Prolene mesh on August 6, 1996, correct?
A Yes, sir.
Q And if somebody wanted a complete picture about the regulatory history, the 510(k) for modified Prolene mesh would be relevant.
MR. LUNDQUIST: Object to form.
THE WITNESS: It could be, at some point when you go -- I think even in my pile I have documents of 510(k)'s that I've pulled, so I wouldn't just look at TVT. I'd look at the components.
BY MR. HUTCHINSON:
Q So the predicate was Prolene mesh.
A Yes, sir.
Q And it's that the same Prolene mesh that was grandfathered in as safe and effective.
A Yes, sir.
Q And FDA found that modified Prolene mesh was substantially equivalent to Prolene mesh, correct?
A Based on what the company told them. The FDA

didn't look at it. They just go on what the document is that the company sends in, and I don't believe that that was cleared as a -- for SUI. It was cleared for filling in spaces that need to have some kind of strengthening, more surgical hernias and abdominal hernias.

Q That's your testimony for modified Prolene mesh, Dr. Parisian?

A I don't recall, but --

Q Wait a minute. I'm just asking, yes or no --

A I don't know.

Q -- is that your testimony for modified Prolene mesh?

A I don't recall that 510(k), in terms of, if it was specially for SUI.

Q And Dr. Parisian --

A And the reason I say that is because there are slings that were made for sacrocolpoplexy that actually had Prolene, people were using surgical mesh. So I don't recall.

Q And Dr. Parisian, you definitely reviewed the 510(k) for TVT, didn't you?

A Yes, sir.

Q And FDA cleared TVT on January 28, 1998?

A Yes.

Q And TVT, it's made of the same Prolene mesh that was grandfathered in as safe and effective, right?

A Yes.

MR. LUNDQUIST: Form.

BY MR. HUTCHINSON:

Q And are you critical of the FDA at all for clearing TVT?

A No, not based on what the process is at the FDA.

Q And you reviewed the updated letter from FDA dated September 28, 2012, didn't you?

A Which letter?

Q It's a letter addressed to Mr. Greg Jones at Ethicon from FDA regarding TVT.

A You mean, to change the product code, or the 522? I don't know if I know that letter. Do I get to see it?

Q Sure.

(Whereupon, Exhibit 13 was marked for identification.)

BY MR. HUTCHINSON:

Q Dr. Parisian, I'll hand you what we'll mark as Exhibit 13 to your deposition.

A Oh, okay. Okay, yes, this is where I got it from.

Q And you've seen that letter before, haven't you?

A Yes.

Q Relied on it in support of your opinions?

A Yes, they corrected their original approval for TVT. They did this FDA in 2012 with most of these SUI products. They changed the product code.

Q I'm sorry, they didn't correct anything; they just changed the product code, correct?

A Correct, yes.

Q Is that correct?

A Yes, that's what I was saying. They changed the product code.

Q And Benjamin Fisher signed this letter from FDA. Did you work with Ben?

A No.

Q You're not critical of FDA or Ben Fisher in any way, are you?

A No. No, they're just putting it under a different code, which is how everything is filed at the FDA, in terms of product. They gave it its own code. They took it from FTL, which was surgical mesh, and now put it over into a code that represents SUI products,

which is -- they gave it OTN, which is mesh surgical synthetic urogynecological for stress urinary incontinence female multi-incision.

Q And you reviewed the TVT-O for this case -- the 510(k) for TVT-O, didn't you?

A Yes, sir.

Q And FDA cleared 510(k) for TVT-O on December 8, 2003.

MR. LUNDQUIST: Form.

BY MR. HUTCHINSON:

Q Yes?

A Was it 2003? You have it in front of you.

Q Is that correct?

A Well, they cleared it.

Q Huh?

A They cleared it, TVT-O.

Q And TVT-O is made of the same Prolene mesh that was grandfathered in as safe and effective?

A Yes.

Q And the FDA found that TVT-O was substantially equivalent to TVT, which had already been cleared, correct?

A Correct, that's what -- based on the 510(k), yes, sir.

Q So that brings us to TVT Secur. FDA cleared this, TVT Secur, on November 28, 2005.
A Yes, sir.
MR. LUNDQUIST: Form.
BY MR. HUTCHINSON:
Q Predicate was TVT and TVT-O.
A Yes, sir.
Q Both of those had been cleared.
MR. LUNDQUIST: Form.
THE WITNESS: Yes, sir.
BY MR. HUTCHINSON:
Q And TVT Secur is made of the same mesh that was grandfathered in as safe and effective?
A Yes.
Q And it's made of the exact same material that FDA approved as safe and effective, correct?
MR. LUNDQUIST: Form.
THE WITNESS: With the NDA back in the 60's, yes.
BY MR. HUTCHINSON:
Q Okay. So the product that Ms. Garcia received was made of the same material FDA approved as safe and effective, correct?
MR. LUNDQUIST: Form.

THE WITNESS: Actually, not totally correct, because one of the things is, yes, it's a polypropylene, but then the laser -- the laser cut actually had changed the mechanical properties of it, but it is the same --
BY MR. HUTCHINSON:
Q I'm talking about the same material. We're talking about the same material.
A It's the same material, polypropylene.
Q Thank you. Well, no, it's the same material Prolene, correct?
A Well, that's the trade name, yes, sir.
Q Okay, and you'll agree with me on that, correct?
A Yes, sir.
Q And the FDA found that TVT Secur was the substantially equivalent to TVT and TVT-O, correct?
A Based on the information that the company provided, yes, sir, and they cited a third predicate, which was the -- was it Gyne Image Sling? -- to address the FDA's question for additional information. So there were three predicates for TVT Secur, not two.
Q And if we look at -- do you have -- I'll hand you what we'll mark as Exhibit 14.
A Thank you.

Q Dr. Parisian, I'm handing you what we'll mark as Exhibit 14 to the deposition.
A Yes, sir.
(Whereupon, Exhibit 14 was marked for identification.)
BY MR. HUTCHINSON:
Q This is the 510(k) for TVT Secur, correct?
A Yes. Yes, sir.
Q And you've definitely seen this document before you walked in here today.
A Yes, sir.
Q Did FDA mess up by telling Ethicon they could market this device?
MR. LUNDQUIST: Form.
THE WITNESS: Not based on the information that was provided, that it was substantially equivalent to TVT-O, TVT, and the third predicate they indicated eventually.
BY MR. HUTCHINSON:
Q And do you fault FDA at all for sending the letter dated November 28, 2005 to Ethicon?
A No, it's a cleared device, based on -- and it's -- based on what they told the FDA, the FDA cleared it. They regulatory would have had to have cleared it.

Q And if we look at -- are you with me on the November 28, 2005 letter?
A Okay, let me find that.
MR. LUNDQUIST: It's the first --
THE WITNESS: Yes, right there, first thing, got it. All right. What do you want?
BY MR. HUTCHINSON:
Q First paragraph that says,
"You may, therefore, market the device, subject to the general control provisions of the Act."
And those are the same general controls provisions we've already talked about.
A Yes, sir.
Q And those are the general controls that provide FDA with the means of regulating devices to ensure safety and effectiveness, is that right?
A Yes, to oversee, as the gatekeeper for devices in the United States, yes.
Q And the general controls refer to adulteration?
A Yes, sir.
Q And misbranding?
A Right. Can't misbrand, can't adulterate.

Q And they relate to good manufacturing practices.
A Right, that's the manufacturer does that, yes, sir.
Q And all of these general controls relate to the safety of the device, is that right?
A Trying to ensure the safety for the public of the devices.
Q Is that a yes?
MR. LUNDQUIST: Form.
THE WITNESS: No, they relate to, the product can be introduced into marketing in the United States. That's what this letter is for, and it goes on --
BY MR. HUTCHINSON:
Q I'm talking about general controls.
A Then you go to the third paragraph, and you can't say --
Q I'm not there yet. Just stick with me, okay?
A Well, general controls --
Q All of these general controls -- wait, I don't want to talk over the court reporter. All these general controls relate to the safety of the device, correct?
A No, they relate to a device that's being marketed in the United States. A manufacturer has to

comply with all those requirements in order for ensure that the manufacturer markets a safe and effective product that's not prohibited by the Act.
Q And --
A It says, "you." It says, "you." It keeps saying "you" to the manufacturer, not the FDA. So these are the general controls, good manufacturing, that the FDA has set up that manufacturers independently have to address in terms of their procedures.
Q And if we look at Exhibit 14 to your deposition, this 510(k) for TVT Secur, this is the information that Ethicon sent to FDA, is that right?
A Yes, sir, and then also additional information. I think that's in this packet.
Q And this is the information that FDA considered before it cleared TVT Secur, correct?
A Sure, yes.
Q Okay. If you look at -- do you remember who signed the Truthful and Accuracy Statement?
A I think it was a Patricia --
Q Hojnoski?
A I think it was.
Q Do you have any criticism of Patricia Hojnoski?

A Yes. I don't think it is truthful and accurate.
Q Have you contacted FDA to alert them that Patricia messed up?
A Well, no.
Q If you look at page ETH.MESH.07876630 -- are you with me?
A 6630.
Q Have you reviewed this document before?
A Yes, sir.
Q And did Ethicon misrepresent anything to FDA here?
A They didn't represent the change in stretch, because that's significant in terms of a surgical mesh. You have to usually characterize the elasticity principles and burst strength. They didn't describe that here. They said it's the same material, but the ends will have this Ethisorb, the Dura Patch.
So they didn't tell the FDA this device is going to be different in terms of the stretchiness and that would come from the laser cut as opposed to the mechanical, and that's an important issue in terms of surgical mesh.
Q Look with me to -- on ETH.MESH 715, if you

have that in front of you.
A I will in a minute. All right. Yes, okay.
Q And this is a Clinical Review done by Dr. Hector Herrera, correct?
A Yes, I helped hire him. So I know him and I trained him.
Q And he's a competent doctor, isn't he?
A Um, yes, he is.
Q If you trained him.
A He is a competent -- he's a urologist by training, one of the few that they have at the FDA.
Q Do you have any criticism of Dr. Herrera?
A No, I have a criticism that he wasn't listened to, but...
Q I'm sorry, he wasn't listened to?
A As a medical officer, he gives his opinions and it's up to the rest of the division who's reviewing. He's not in the same division.
Q Was Dr. Herrera diligent and smart?
A Yes, I think he's right. They needed to give data.
Q Was he an honest doctor?
A Yes.
Q And did you work with him at all at FDA?

A Yes, I -- I --
Q After you hired him.
A Yes, but he's a part-time, he's an older urologist. He was -- he had retired from urological practice.
Q And if you'd look at the next page, 716, last paragraph, it says,
"With the company's response to prior deficiencies, I do not have any urological clinical issues to preclude approving the submission."
Do you see that?
A Um-hum.
Q Did he get it wrong?
A No, not based on the process, because they came up with a subsequent 510(k) that showed that they had actually already approved it, the Gyne Ideas Minitape, which makes it so the FDA can't really ask for clinical studies if they've already got a predicate.
Q Are you aware of anything Ethicon hid from Dr. Herrera or misrepresented to Dr. Herrera?
A Well, yeah, they misrepresented the European experience and the KOLs were not having a good time putting this in, and that the IFUs were inadequate and

that there were safety issues.
Now, this is to get cleared. This device got cleared. The issue really for Ms. Garcia is post-market.
But they did not -- and they did not tell Dr. Herrera about the change in the mesh, the difficulty with using the inserter, and they are basing their argument on that they're substantially equivalent to TVT and TVT-O.
And so he had to accept, based on what their representations were from the expert, the company, that they had satisfied his concerns.
(Whereupon, Exhibit 15 was marked for identification.)
BY MR. HUTCHINSON:
Q Let's look at what I'll hand you to be marked as Exhibit 15 to your deposition, and you have reviewed this document before today, haven't you, Dr. Parisian?
A Let me look at it and make sure.
Q Okay. Yes?
A Yes, this is for the PMA, when it was still a PMA.
Q And if you'll look with me on ETH.MESH.09634315 -- and by the way, before we get to

that document, this is a letter dated October 7, 1988 from FDA, is that right?
A Right.
Q And it's about the same NDA 16374 that we've been talking about?
A Correct --
Q The Prolene suture.
A -- and it's been transitioned with the Supplement 34 -- you have so many supplements -- Supplement 34, and it's now being reviewed as a PMA by CDRH.
Q And the page that I referenced you to, that's the package insert that Ethicon sent FDA, correct?
A For Prolene, yes, sir.
Q And it says, under Actions, "The suture...." Are you with me?
A Yes.
Q It says,
"The suture is not absorbed nor is it subject to degradation or weakening by the action of tissue enzymes."
Is that correct? That's what it says?
A Yes, sir, that's what it says.
Q And that's the exact language in the IFU for

TVT Secur about degradation.
A Correct, I said that it came from the suture.
Q Right.
A Came from Prolene suture.
Q And that exact language was sent to FDA, back in 1988 and before that?
A Yes, it's a PMA supplement for a suture material.
Q I'm sorry, is that correct?
A Yes, sir.
Q And that exact language was reviewed by FDA, correct?
A Yes, based on the 1969 clearance, which technology and biochem have changed a lot, but yes, that is an approved language carried over from the original NDA approval.
Q Correct, and that exact language was approved by FDA, correct?
A As a drug. It wasn't re-approved, it was -- what was the indication? It was -- because FDA didn't go back and re-look. Let me look at the label. They wanted to have an updated labeling changes for the size 7-0 Prolene clear and pigmented sutures. So it was only basically to change the labeling for the clear and

pigmented sutures.
Q You're not critical of FDA in any way for approving that language, are you?
A No. I don't have the prior label. I have this label. So I don't know if that actually had been -- if it had come from the NDA or if it actually had been changed in this PMA.
Q But that exact language is the same language about degradation in the current TVT Secur IFU, correct?
A Right, it's appropriate for a suture.
Q If -- let's talk about your experience with the FDA a little bit. Back 20 years ago when you worked at the FDA, did they start out to have safe products cleared?
MR. LUNDQUIST: Form.
THE WITNESS: Yes. They still do, as far as I know.
BY MR. HUTCHINSON:
Q And when you worked at FDA, you didn't want to -- an unsafe product to be cleared, did you?
A There are legal limitations, like there are products that are unsafe, like Class III devices that still haven't been classified by FDA, the safety and efficacy is not known. So you're bound by what the

requirements are for certain products. You didn't want to hurt people, you wanted to have the public protected, but you're also limited in terms of what you can request.
Q When you worked for FDA --
A In that period, that got worse even in 1997, when the Lewis Ferguson actually got passed.
Q When you worked for FDA, Dr. Parisian, did you work alongside competent professionals?
A Yes.
Q FDA could have refused to clear modified Prolene mesh, correct?
MR. LUNDQUIST: Form.
THE WITNESS: They could have, but why would they?
BY MR. HUTCHINSON:
Q FDA could have refused to clear TVT or TVT-O or TVT Secur, correct?
MR. LUNDQUIST: Form.
THE WITNESS: Yes, they could have.
BY MR. HUTCHINSON:
Q And do you know how many transvaginal mesh slings FDA has cleared, sitting here today?
A Quite a few.

Q Give me your best estimate.
A I don't know. We're talking about many -- I wouldn't be surprised if it was in the hundreds --
MR. LUNDQUIST: Form.
THE WITNESS: -- in terms of all the different 510(k)'s and supplements and, yeah, changes.
BY MR. HUTCHINSON:
Q FDA has never recommended any labeling changes for TVT Secur, has it?
A I haven't seen any. I don't know if they have or not.
Q And FDA has never recommended any labeling changes for any of the TVT family of products, have they?
A I don't know. I mean, I would have to -- only the FDA and Ethicon would know that.
Q What you do know is that FDA has never determined that TVT Secur labeling was false or misleading, is that --
A Why would they? They never had to review it.
Q My question is a yes or no. Then you can explain.
A No, they have not. That doesn't change my opinions, because they had no reason to ever review it.

It's up to Ethicon to have made an adequate label.
Q FDA has never determined that the labeling of any of the TVT family of products is false and misleading.
A That's correct. They've done some other action where they send out a safety -- a public health notification, so it's actually taking it kind of one step higher. FDA is actively involved in the labeling and information being given to physicians and patients.
Q And because FDA is actively involved, they have never determined that the TVT Secur device was misbranded, have they?
A I don't think they've ever reviewed it to look at that. That would be a --
Q Well, I'm not talking about what they reviewed. I need a yes or no: FDA has never determined that TVT Secur device was misbranded.
A That is correct, because they've never looked at it, as far as I know.
Q And in fact, FDA has never considered or determined that any of the TVT family of products have been misbranded, have they?
A Not that I'm aware of.
Q Misbranding, that's a specific finding by FDA.

Yes?
A No, it's --
Q No?
MR. LUNDQUIST: Form.
THE WITNESS: It's just -- it's a legal finding by the FDA, but it's described in the Act for the manufacturer, in terms of misbranding, adequate instructions for use of warnings. It puts it on the manufacturer, not the FDA, to make sure that they're not misbranded, and that even in the approval letters, the clearance letter you showed me before, it said it's up to the manufacturer to ensure that they don't misbrand, adulterate.
So it's under -- and we're talking 21 U.S.C. 352. So that's the manufacturer's job. It's not up to the FDA. The FDA may fine somebody who's misbranded and bring charges or make a warning letter saying that, but it's really the manufacturer to ensure they don't misbrand their product.
MR. HUTCHINSON: Move to strike as nonresponsive.
Q FDA -- strike that. Misbranding is a legal finding by FDA, correct?
MR. LUNDQUIST: Form.

THE WITNESS: Well, in two components. It's --
BY MR. HUTCHINSON:
Q Is that -- I'm sorry. You can explain your answer, but I need you to say yes, yes or no.
A I'm going to say I can't say yes or no, because one, I'm not an attorney and you're asking me a legal decision.
Q Well, I'm just using your words.
A No, but in terms of a manufacturer, in terms of the Act and as a consultant, I consult with manufacturers as to whether they've misbranded in terms of the requirements for adequate instructions and warnings.
So there's two different components: Are you misbranding? The FDA may make a legal decision or it may not. The manufacturer is the gate that should determine misbranding.
Q But if the FDA believes that a product is misbranded, it can make the manufacturer change the label, can't it?
A No.
Q No?
A No.

Q It could make the manufacturer take the product off the market, can't it?
A Only under certain requirements. It's the --
Q I'm sorry, is that a yes?
A Under certain requirements.
Q Wait --
A No, I can't answer yes or no --
Q Okay.
A -- because they're --
Q Well, wait just a minute, let me talk. I don't want to talk over the court reporter, okay?
If FDA believes that a product is misbranded, it can tell the manufacturer, or make the manufacturer take the product off the market, correct? Yes or no, then you can explain.
MR. LUNDQUIST: Form.
BY MR. HUTCHINSON:
Q That's something the FDA can do, yes?
A They can technically do it, but rarely do it, because it takes --
Q Move to strike as nonresponsive.
A Well --
Q They can do it, can't they?
A They can, but technically, they don't. They

would rather get voluntary compliance. Like, they will send a warning letter. A warning letter will say you're misbranding. There's no legal action, but it's a notification that the FDA considers you misbranding. They're not going to take the product off the market because of misbranding. They're going to -- the manufacturer is -- it's assumed that the manufacturer won't want to not comply with the Act --
Q Let's go back --
A -- notification. So they did voluntarily comply --
Q Let's get -- let's go back to FDA. The FDA never concluded that Ethicon had failed to provide safety information to FDA, did it?
MR. LUNDQUIST: Form.
THE WITNESS: I don't know. All we can go on is what the FDA has put in writing. We don't know what the FDA concluded, but they did ask for a 522 study and the company chose not to do it.
BY MR. HUTCHINSON:
Q FDA never concluded that the TVT Secur's labeling was inconsistent with the medicine or science.
A No, that's not correct. In terms of the public health notification, they looked at the entire

industry --
Q Let's talk about the Secur, okay?
A Well, they didn't focus on the Secur, they talked about the SUI industry in terms of mesh --
Q All right, so let's --
A -- and they re-classified it.
Q Stick with me, let's stick with my question. On TVT Secur's labeling, FDA never concluded that that labeling was inconsistent with medicine or science.
MR. LUNDQUIST: Form.
THE WITNESS: You know, I don't know what FDA concluded other than they asked for a 522 post-market safety study.
BY MR. HUTCHINSON:
Q FDA never requested that TVT Secur be withdrawn from the market.
A That's true.
Q And FDA never declared that TVT Secur was illegally marketed.
A That's true, it was cleared. I've never said it was illegally marketed. I'm saying it wasn't marketed -- the cleared device, in terms of the clearance.
Q When we talk about the 522 order, you've

reviewed that, is that right?
A Yes.
Q That has nothing at all to do with a recall, does it?
A No, no, it's to get post-market safety information, long-term data, to add to the label, update the label, which is one of the things that I said needed to be done.
Q A 522 order has nothing to do with punishing a company, does it?
A No, and it's usually industry-wide, in terms of, the 522 was issued to all the surgical mesh industry for their products.
Q And this 522 order, it was industry-wide, wasn't it?
A Yes, sir.
Q And it was sent to all manufacturers of mini slings?
A Right. To continue marketing, right.
Q Not just Ethicon.
A That's right.
Q And about -- do you know how many companies received -- different companies received a 522 order?
A Quite a few, because every product had to have

a 522 order.
Q My question is: Do you know how many companies received a 522 order?
A No.
Q Would it surprise you if it was over 25?
A I thought it was more than that. So no, it wouldn't surprise me if you just say 25.
Q In fact, do you know that FDA issued over 100 522 orders?
A See, that's what I was thinking more, yes, sir.
Q So Ethicon just wasn't just singled out on this 522 order, were they?
A No, no, the entire industry was, particularly for the single-incision sling.
Q You don't know why Ethicon stopped making TVT Secur, do you?
MR. LUNDQUIST: Object to form.
THE WITNESS: I do based on the documents, in terms of the failure of the product and the safety issues. They said they de-commercialized it, but actually it was less safe -- it was less safe than TVT-O. There was no real advantage for a physician to use TVT as compared no TVT-O, in terms of the potential

risk. The Australian physicians didn't even want to be re-trained in it, and it was not -- it was not a big seller. Physicians had stopped using the product.
So it was a safety issue. It should have been recalled long before Ms. Garcia was actually implanted, but they chose not to go ahead with the 522 study based on saying the complexity of the study.
BY MR. HUTCHINSON:
Q Dr. Parisian, let's talk about the MDRs for just a minute and your prior testimony about MDRs.
You know the difference between an MDR and an issue report, don't you?
A Sure. An MDR is filed by the company.
Q And an issue report is not filed by the company, is it?
A No.
Q And did you review any issue reports in this case?
A Not specifically called issue reports. Are you talking about CAPA reports, when the company is looking at safety issues?
Q Have you ever looked at Ethicon's policies and procedures for monitoring medical devices?
A At various different litigations I have, yes.

Q Okay, I'm talking about for this litigation. That's not in your reliance material, is it?
A No, that's in my training of having been involved with Ethicon products in terms of marketing. The only thing I saw was a 15 to 20 percent ceiling in terms of complaints, and they tend to have an acceptable minimum that can be filed every month in terms of things -- it goes along with --
Q How long ago has it been since you looked at Ethicon's policies and procedures for monitoring medical devices? How many years?
A I'd say, maybe two.
Q You did that in the context of other litigation?
A Yes, sir.
Q But you didn't do that in the context of this case, is that right?
MR. LUNDQUIST: Form.
THE WITNESS: No, sir.
BY MR. HUTCHINSON:
Q Am I correct?
A Yes, sir.
Q Are you intending to offer any opinions that Ethicon received a product complaint and did not

appropriately report it to FDA?
MR. LUNDQUIST: Form.
THE WITNESS: The only way I could do --
BY MR. HUTCHINSON:
Q Hold on just a minute. I'll let you explain your answer, but start with yes or no, and then explain for me, please, ma'am.
A At this point in time, I would say no.
Q Okay.
A Because I haven't been given specific complaint files, which you know is different than an MDR. So the only way to know if something wasn't filed is you have to go through each complaint file and see if it actually was filed as an MDR. So that's why I'm not planning to do that, because I haven't received all the complaint files.
Q So fair enough. As we sit here today, you have no opinion whatsoever that Ethicon received a product complaint and didn't adequately report it to FDA.
MR. LUNDQUIST: Objection.
THE WITNESS: Well, I do. In terms of the numbers of MDRs, we know that they're receiving complaints. A specific --

BY MR. HUTCHINSON:
Q Well, stick with my question.
MR. LUNDQUIST: She is answering your question.
THE WITNESS: No, in terms of the volume of complaints that are being received and discussed internally, the MDRs that I pulled up are not consistent with that same pattern. So we know there were things not being filed.
I haven't gotten to go through the complaint files specifically and look at them in terms of failure to file, but I haven't seen Mrs. Garcia's MDR. There should be an MDR filed for Ms. Garcia, and I hadn't seen that at that point in time. I don't -- I don't know if anyone knows where it is, but there should be something. So I can't talk about it without having -- knowing that she actually had one filed.
MR. HUTCHINSON: Move to strike as nonresponsive.
Q Dr. Parisian, are you offering any opinion that Ethicon received a product complaint and didn't adequately or appropriately report it to FDA?
MR. LUNDQUIST: Form.
THE WITNESS: I think I've explained that at

this point in time I haven't received complaint files, which I can do, but I haven't been asked to do that, and in Ms. Garcia's point, I haven't specifically received her MDR.
BY MR. HUTCHINSON:
Q Are you testifying that Ethicon withheld anything from FDA?
A No -- well, in terms of, did they fully communicate so that FDA could fulfill its role, I don't believe they did, as I talked about, in the 510(k). I don't think the risk information came through --
Q I'm not talking about 510(k)'s. Stick with me for just a minute. I'm talking about product complaints, MDRs, okay?
A Well, based on my review, my really superficial review, there was not the type of MDRs that you would expect to see from the company documents.
Q My question is: Are you testifying, or do you have any opinions, that Ethicon withheld anything from FDA regarding product complaints? Yes or no.
MR. LUNDQUIST: Object, form.
THE WITNESS: I think I've answered it, based -- it will have to be a very general, that in terms of the documents I'm seeing, particularly in 2007,

the MDRs are not there, in terms of, filed with the FDA.
BY MR. HUTCHINSON:
Q So you think -- so you think FDA -- I'm sorry, strike that.
You think, just because of the numbers of MDRs that you're seeing in 2007 --
A Of premature failure.
Q -- that Ethicon is not adequately reporting product complaints to FDA? Is that your testimony?
A Based on that --
Q I'm sorry, is that your testimony?
A Yes, sir. Based on that information today, to actually hone it in, I'd have to look at the complaint files and compare them one-to-one as to what you're reporting.
Q And that's something you've not done so far, is that correct?
A That's right.
Q Do you believe that Ethicon had a proper safety surveillance department?
A No, and that's based not on this case, but on having seen the other cases that I've been involved in. They tend not to report something that's included in the label. If the word "erosion" is in the label, it's not

going to be reported by the procedure. So I would need to look at that in more depth, but at this point in time, the information suggests that they're not adequately surveilling, or -- updating physicians and FDA on the risk that's being reported personally.
Q Can you tell me name of a person who you think did something wrong at Ethicon's post-market surveillance group?
A I don't think anybody did anything wrong. I think that --
Q Hold on just a minute. I'm sorry, can you --
A I don't have a person's name that --
Q Okay.
A -- did something wrong. I think that --
Q Can you tell me the name -- hold on just a minute -- can you tell me the name of anybody at Ethicon's post-marketing surveillance group that did something well?
A I don't know any of the names in that group, and the issue is that they're following procedures, and Ethicon has unique procedures in terms of filing of MDRs.
Q So you can't give me, sitting here today, you can't give me a specific example of anything that

Ethicon may have done to violate an MDR reporting requirement, correct?
MR. LUNDQUIST: Object to form.
THE WITNESS: Only --
BY MR. HUTCHINSON:
Q Hold on a minute.
A Yeah, I cannot, in terms of the documents and the reports of perforation, and --
Q I'm not talking about the documents. I'm talking about a specific case example. Can you give me one specific case example of a violation?
A Um-hum.
MR. LUNDQUIST: Form.
THE WITNESS: No, and as I said, I haven't seen Ms. Garcia's MDR. So there should be an MDR for her.
MR. LUNDQUIST: Are we at a good breaking point?
MR. HUTCHINSON: Give me just one --
MR. LUNDQUIST: Okay, we've been going -- that's fine, whatever you need.
MR. HUTCHINSON: Give me five minutes?
THE WITNESS: Sure.
MR. LUNDQUIST: Whatever you want.

THE WITNESS: Go for it.
BY MR. HUTCHINSON:
Q Let's talk about your device work with MD Assist. That company's still in existence?
A Yes, sir.
Q You're the sole shareholder?
A No, my husband is, too.
Q You and husband own it, right?
A Yes, he gets all the monies, I get all the work. We won't tell him.
Q Has he had a chance to spend any of the money you make testifying for plaintiffs?
A Has he?
Q Yes.
A He has all the money. I'm busy doing -- I don't get...
Q When is the last --
A He's an anesthesiologist and does all the billing and handles all that stiff.
Q When is the last time MD Assist did any regulatory consulting work for a medical device company?
A It would have been last year. I had to cut off even the manufacturers. I just don't have time and I'm trying to cut back.

Q And you don't have time because your full-time job now is to do the litigation work, like we're here today on, correct?
MR. LUNDQUIST: Object.
THE WITNESS: Well, no, I'm trying to retire, and so I'm trying to not take new issues on. I'm getting old.
MR. OLIVEIRA: I know how you feel.
THE WITNESS: And I'll swear to that.
BY MR. HUTCHINSON:
Q MD Assist has never done any consulting work for a pelvic floor product, have they?
A No, not for a pelvic floor.
Q MD Assist has never had a surgical mesh product approved by FDA.
A They're not approved --
Q I'm sorry, cleared. Cleared.
A That's correct.
Q All right. MD Assist has never been involved with the submission of a 510(k) for a device where it was surgical mesh.
A I believe that's correct.
Q And MD Assist has never been involved in the design of a medical device where part or all of it was

surgical mesh.
A That's correct.
Q Never been involved in any clinical trial to evaluate the safety and efficacy of surgical mesh?
MR. LUNDQUIST: Object.
THE WITNESS: That's correct.
BY MR. HUTCHINSON:
Q Never been, or -- performed a DDSA for surgical mesh.
A As far as I can recall. You mean at a company? That's correct.
Q Never performed an FMEA for a device where part of all of it was surgical mesh.
A That's correct.
Q And in fact, never worked on any medical device that was designed specifically for a urogynecological indication.
MR. LUNDQUIST: Form.
THE WITNESS: Not at the FDA.
BY MR. HUTCHINSON:
Q Is that correct?
MR. LUNDQUIST: Form.
THE WITNESS: Other -- you said a surgical -- if you say a surgical, that's correct, because surgical

you're -- because I did --
BY MR. HUTCHINSON:
Q A surgical urogynecological device, correct?
A That's correct.
MR. HUTCHINSON: All right, so....
MR. LUNDQUIST: Five minutes?
MR. HUTCHINSON: Will's going to take a break, so we'll take a quick five.
(Deposition in recess from 2:39 p.m. to 2:59 p.m.)
MR. HUTCHINSON: Back on the record.
Q Dr. Parisian, we're back from a break. You'll agree that lawyer advertising can stimulate reporting of adverse events, correct?
A It can be one of the things, yes, sir.
Q With regard to the adverse events that you accessed on the MAUDE database, can you identify how many of those adverse reports were filed by attorneys representing plaintiffs in mesh litigation?
A There were filed by the companies and they said they were notified by attorneys, so....
Q And can you identify how many of those were?
A No, sir. But that doesn't mean events don't happen.
Q You'll agree FDA recognizes that submissions

of an MDR does not mean that the product caused or contributed to that injury, correct?
A That is a statement that is, I think, in the regulations.
Q That's something you would agree to?
A Yes. Otherwise, nobody would file any MDRs.
Q And you'll also agree, which is consistent with your testimony before, that oftentimes an MDR is incomplete.
A There are incomplete MDRs filed with the FDA, yes, sir.
Q And you can't draw any conclusions from MDRs about causation, can you?
MR. LUNDQUIST: Object, form.
THE WITNESS: It depends on what the MDR says. I mean, you can't make a blanket statement, but you can't come up with an incidence rate based on an MDR, on the MDR database.
BY MR. HUTCHINSON:
Q Okay, and you have no evidence that Ethicon failed to report to FDA any adverse event report that it received.
MR. LUNDQUIST: Object to the form.
THE WITNESS: Other than that there wasn't any

filing, and I'm seeing all these documents where there's erosion failures perforations, and there are no MDRs.
BY MR. HUTCHINSON:
Q But no evidence. You have no evidence to suggest that, correct?
MR. LUNDQUIST: Object to form.
THE WITNESS: I think that is evidence, in that the MDRs are only getting filed in 2013. So the database is not consistent with the information that the company's considering, particularly in 2007, 2008. There's nothing about the Australian cases or the German cases in the MDR database.
BY MR. HUTCHINSON:
Q And that's all the evidence that you have, correct?
A Well, that's significant evidence, because I'm looking at the records internally, which is the evidence --
Q Hold on just a minute. I'm not asking for significant. I'm asking, is that all the evidence you have?
A That's significant information, yes. That's why I would support that the trends in the MDR, not -- the trends, for the Secur particularly, is not

consistent with the internal picture.
Q And you can't give us one example of a patient having a product complaint and that product complaint not being reported to FDA, can you?
MR. LUNDQUIST: Form.
THE WITNESS: I'm going to rely --
BY MR. HUTCHINSON:
Q I'm sorry?
A Yes, I think I can.
Q Tell me the name of that patient.
A Well, I don't know name of the patient.
Q Can you give us --
A I know they --
Q Hold on just a minute. Stick with me. Can you give us one example of a patient who had a product complaint and that product complaint did not get reported to FDA?
A The 49 patients in Germany that were not reported to FDA in 2007, the Australian patients that weren't submitted to the FDA, because the issues and the frequency and the severity is not in the labeling in 2007. So those should have been reported to the FDA.
Q Let's go to your Exhibit 7, please, and that's the patient brochure.

A Exhibit 7, okay, got it.
Q You've reviewed this and relied on it in forming your opinions, correct?
A Actually, I reviewed the 2008 patient brochure. That's in one of my books, here.
Q And --
A But this is relevant to Ms. Garcia. It's 2011.
Q And this would be -- hold on just a minute, Dr. Parisian.
A Yes, sir.
Q Dr. Parisian -- Dr. Parisian -- this patient brochure that was marked as Exhibit 7 would have been the one that Ms. Garcia would have received prior to her surgery, correct?
A Right, I said this would have been the relevant one to her, because it's 2011, but I saw 2008.
Q Do you have any criticisms about this patient brochure?
A Yes, the criticisms are similar to the IFU, in terms of, when we were talking about for the physician, the types of the warning information.
I do have one good statement about Ethicon in that they did include a heading about risks, basically,

what risks. So that was good. So you asked me before for something good, and --
Q Move to strike as nonresponsive.
A No, no, I was trying to --
Q Let's talk about your criticisms to the patient brochure that we've marked as Exhibit 7.
Would you list any criticisms that you have about the patient brochure marked as Exhibit 7?
A Yes. I would reference the same adverse event information that's missing in the IFU, the same type of information the document discusses on page 19.
And one of the things that I didn't mention before that would be relevant and germane to a woman's brochure is the pain on intercourse for her partner, that that is a -- either in the physician's IFU or in the patient's information, and I think it's also in Dr. Miklos' description, so --
Q So your testimony is that this patient brochure should warn about dyspareunia to a woman's partner?
A No -- yes. Oh, yes, in terms of -- not dyspareunia, that's her pain, but a male inserting his penis can actually feel -- there's been reports of that, particularly from Ms. Garcia. So the pain on

intercourse for the partner, a woman needs to know about that. That's a big issue if you've got a partner and he's going to have pain every time he has sex with you.

Q Let's talk about your criticisms. Have you told me all of your criticisms about the patient brochure marked as Exhibit 7?

A Well, I tried to simplify it. It's fairly similar to the types of problems I had with the IFU, in terms, specifically for the adverse events, the permanency, that this is not transitory, which is right there, and I would also refer you to Dr. Miklos, because he goes through, from a physician's point of view, the types of information he thinks should be in the label in terms of what a physician needs to know, and I would put it in terms a patient could understand.

Q Do you remember when we talked about the IFU, you listed to me at least 28 specific criticisms you have of the IFU? Do you remember that testimony?

A Yeah, I went -- yes, I went through the label, trying to give you both the opinion and then what kind of information I would use to correct it.

Q And how many specific criticisms do you have about the patient brochure?

MR. HUTCHINSON: Form.

THE WITNESS: Well, the patient brochure is not a design issue. It actually has indications, contraindications, precautions. So I would move that forward in the beginning for a woman, but the design in terms of the brochure is a little better than the physician's IFU, but the adverse reaction information should be the same, again, warning about the permanency of the issues, just like I described for the physician IFU.

But it has to be written in terms that a woman, a non-physician, could understand, a lay person could understand. It's -- it would be an example of direct consumer labeling. So it needs to be in information that a consumer could understand.

BY MR. HUTCHINSON:

Q How many specific criticisms do you have about the patient brochure?

MR. LUNDQUIST: Form.

BY MR. HUTCHINSON:

Q You listed 28 or more for the IFU. How many for the patient brochure?

MR. LUNDQUIST: Form.

THE WITNESS: Okay, one of the things about this brochure as opposed to the IFU is, this is called a

"family," "TVT family" product. So it really isn't specific for TVT Secur. The company is aware internally that there's differences in risks for the TVT Secur versus the other products --

MR. HUTCHINSON: Move to strike as nonresponsive.

Q Doctor, stick with me and listen to my question.

A That's one.

Q Okay, that's one. All right, I'm asking you to quantify, and if you don't understand my question, please let me know, but I'm asking you to quantify: How many specific criticisms do you have about the patient brochure?

MR. LUNDQUIST: Object to form.

THE WITNESS: I'm thinking. I would put -- just two, I would put the pregnancy information over by itself --

BY MR. HUTCHINSON:

Q I'm sorry, did you say two?

A Two.

Q And what are they?

A The pregnancy information would be taken away as a specific population all to itself, because it

doesn't apply to most women who are getting SUI procedures.

Q What would the second -- I mean, the second -- strike that. What would the second --

A Third. Third.

Q Well --

A First was that it should be separated out as a --

Q Wait a minute. I don't know if you and I are communicating. I want to know how many specific criticisms you have about the patient brochure, and I thought you told me two.

A No, no, I told you the second one.

Q Okay, all right. So my question is, how many specific -- I want you to quantify this, and if you don't understand the question, let me know, but I'm asking you to quantify, how many specific criticisms do you have about the patient brochure?

MR. LUNDQUIST: Object to form.

THE WITNESS: I would say we were up to two. So I would say, in a short answer, I can do it in -- as four. So the third criticism would be --

BY MR. HUTCHINSON:

Q Okay, hold on just a minute. I'll get to that

in a minute, but I want to make sure I understand. You have four specific criticisms about the patient brochure, correct?

A Yes.

Q All right, do you have any others?

MR. LUNDQUIST: Form.

THE WITNESS: No.

BY MR. HUTCHINSON:

Q All right. So tell me what your four criticisms are about the patient brochure.

A Okay. We've already done one, we've already done two.

Q All right. Number one was the pregnancy.

A No, no --

Q I'm sorry. Number one was --

A That Secur should be separated out, in terms of the --

Q Okay, Secur should be separated out.

A Because its risk is unique compared to the other product.

Q Wait just a minute. The court reporter is not keeping up with us. Number one is, the Secur should not be separated out.

A No, it should.

Q I'm sorry, it should be separated out. The second one was pregnancy, right?

A In its own special population, taken out of the --

Q Okay, what's the third one?

A The third are the inadequacies of the warnings for the user, as I described for the IFU, but in terms that a patient could understand.

Q Okay, and what's your fourth one?

A The fourth are the adverse events are inadequate, just as I described in the IFU; and then I would also reference Dr. Miklos' report on page 19, where he talks about, from a physician's point of view, what information needed to be in the labeling, and I would put that all in terms of a label that a patient could understand.

Q And if Dr. Miklos has opinions about the IFU and the patient brochure, your opinions about the IFU and the patient brochure would be cumulative, wouldn't they?

MR. LUNDQUIST: Form.

THE WITNESS: Pardon? I don't understand that.

// //

BY MR. HUTCHINSON:

Q You don't understand?

A I don't understand what that is, what your question is on that.

Q They would be duplicative. You're giving opinions about the same topics.

A Oh, you mean --

Q It would be cumulative.

A Cumulative.

MR. LUNDQUIST: Form.

THE WITNESS: I would rely on Dr. Miklos, in terms of the information that he as a physician thinks should be in the labeling is consistent with the type of information I described before, but the -- the adverse events --

BY MR. HUTCHINSON:

Q Just a minute, stick with me. But that would be cumulative, wouldn't it?

MR. LUNDQUIST: Object to form.

THE WITNESS: Cumulative, yes, but I don't understand why you're asking that.

BY MR. HUTCHINSON:

Q If -- when you reviewed the patient brochure, did you notice anything that Ethicon did well --

A Yeah.

Q -- in drafting the patient brochure?

A I was trying to tell you what they did well, but you didn't want to hear it.

I thought what was good was, from the 2008 to the 2011, they actually did add a section, which I think they might have wanted to put up front, about risk, and I thought that was a good addition in terms of a label, on page -- it's not totally complete, but on page 12.

And some of the information in the risk information is not conveyed in the adverse event reports. It's not -- they should cover each other. If you're describing these particular risks, then some of the adverse event reports or adverse events that I'm saying is missing should reflect information that they put in this risk section. So the risk -- starting the risk section was a good thing.

Q Did you see anything else that Ethicon did well in the patient brochure marked as Exhibit 7?

A Well, they spelled Gynecare and TVT right, but I think that --

Q Anything else?

A It's a better -- they're improving their label since the 2008 label, but they still are not conveying

the specific risks for the TVT Secur, which is different than the other products. They're just putting them together in the TVT family. Even internally that was questioned when the company was saying, are we really going to have a TVT family that includes TVT Secur?

So I think that that would be my number one, but I think it was right to have questions for your doctor, but they needed to improve the adverse events to make sure that the woman knew that these were permanent risks, such as chronic pain, dyspareunia, change in the vagina, things like that. And I think I captured that before when I talked about the IFU for the physician.

Q You're not an expert on Prolene, are you?

A What do you mean by "an expert on Prolene"? I mean, you've seen I've gone through the regulatory history of Prolene, so I don't know if.... There is a regulatory expertise that I have on Prolene.

Q Would that be the only expertise that you have on Prolene?

MR. LUNDQUIST: Form.

THE WITNESS: I've used Prolene suture, so I don't know, what do you mean, in terms of Prolene?

BY MR. HUTCHINSON:

Q Do you hold yourself out as an expert on

Prolene?

A In terms of the regulatory issues that would be considered, FDA regulatory, on Prolene.

Q And that would be all, is that correct?

A As a physician --

Q I'm sorry. And that would be all, correct?

MR. LUNDQUIST: Form.

THE WITNESS: I believe that's the only role I would have here in terms of Prolene.

BY MR. HUTCHINSON:

Q Okay, and --

A And as a pathologist and as having looked at tissue slides, you know, animal studies, so -- but that would be regulatory, too. That would be -- I guess you would call that a toxicology point of view.

Q The FDA advisory panel has never recommended removing any mesh product from the market, correct?

A The advisory panel? I believe that's correct. They didn't even -- you're talking about advisory panel where they talk about SUI and POP? Yes, they asked for data.

Q The National Institutes of Health has never recommended removing any mesh product from the market, has it?

A They wouldn't. They would recommend not using it, but they wouldn't recommend removal.

Q And they have never recommended not using TVT Secur, have they?

A I don't know what the NIH -- I haven't looked at what the NIH has said about TVT Secur.

Q The American College of OB-GYN has never recommended removing any mesh product from the market, has it? ACOG.

A A specific mesh --

Q We're referencing ACOG, A-C-O-G.

A Not that I recall. They have guidelines, they don't talk about removal of a device.

Q The American Urogynecologic Society, or AUGS, has never recommended removing any mesh product from the market, has it?

A I believe so. I don't see that that would be their role, either.

Q I'm correct?

A Yes, sir. I said, I believe so.

Q And you would agree that a ban on the use of synthetic mesh products would prohibit many women from accessing treatment options?

A A ban, for many indications -- they use

surgical mesh for a lot of --

Q Stick with my question.

A I didn't --

Q You would agree that a ban on the use of synthetic mesh products would prohibit many women from accessing treatment options, correct?

A That's a very generic statement. It's not the --

Q I'm asking you. Correct?

A If FDA banned all surgical --

Q Just a minute. Wait a minute. I don't want to talk over the court reporter.

A No.

Q You would agree, correct, Dr. Parisian? Yes or no.

MR. LUNDQUIST: Form.

THE WITNESS: Well, let me ask --

BY MR. HUTCHINSON:

Q I'm the one asking questions today.

A I know, I want to answer. I'm asking for a clarification.

Are you saying -- what I think you're saying is, if FDA were to ban surgical mesh, that would deny women treatment options, generally? Yes.

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Q Let me hand you what we'll mark as Exhibit 16 to your deposition.

(Whereupon, Exhibit 16 was marked for identification.)

THE WITNESS: So do the colors have any indication, on the clips? That's a black.

MR. LUNDQUIST: What?

MR. HUTCHINSON: I got a black clip. That means it's a very important document, one I suspect you'll probably disagree with, but we'll try to -- we'll try to go through it.

Q I've handed you what's been marked as Exhibit 16 to your deposition. Do you see that?

A Yes, sir.

Q In fact, this is a document you relied on in reaching your opinions, is that right?

A I've seen this, yes.

Q And AUGS, that's an association of surgeons who treat SUI.

A That would be that group, yes, sir.

Q Has over 1700 members.

A Yes.

Q It includes urologists, gynecologists and urogynecologists, correct?

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A Right, and it includes the SFU -- SSFU.

Q And that's another society, true?

A Right, Society of Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction.

Q And you're not a member of either one of these, are you?

A No, sir.

Q And if we look on page 2, paragraph one, in bold it says, "Polypropylene material is safe and effective as a surgical implant." Do you see that?

A Yes, sir.

Q Do you agree with that statement, Dr. Parisian?

A Yes, sir.

Q Okay, and if we look at --

A And look at, they talk about the different specialties, and they're talking about the general polypropylene, yes, sir. We've talked -- that it's been approved, FDA, polypropylene, surgical implant. It can be a suture, it can be anything.

Q And if we look at -- if we look at paragraph four -- I'm sorry, if we look at paragraph two, the monofilament polypropylene mesh, MUS, that stands for mid-urethral slings, correct?

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A Yes, sir.

Q And that's what Ms. Garcia has got, right?

MR. LUNDQUIST: Object to form.

THE WITNESS: Um --

BY MR. HUTCHINSON:

Q Dr. Parisian --

A Let me look at this, because they often make a differentiation between the SISMUS and the MUS. Let me just see what they're talking about.

Q All I'm asking you is: Is your opinion that Ms. Garcia got a mid-urethral sling?

A Yes, single-incision mid-urethral sling.

Q And paragraph 2 says,

"The monofilament polypropylene mesh MUS is the most extensively studied anti-incontinence procedure in history."

Do you agree with that statement?

A Where --

Q Paragraph 2.

A Paragraph 2.

Q The bold.

A Oh, all the heading. I thought you're talking about the --

Q Do you agree with that statement?

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A Yes, that's what the group said at the advisory panel. The FDA disagreed, that they needed more safety information, but this group of physicians said that they were satisfied that it's been studied. FDA didn't agree with that at the panel meeting or in its subsequent documents. That's why they're trying to get data. They didn't ask for a 522 for those products. They expected the --

Q Move to strike as nonresponsive.

Paragraph 4 says,

"The FDA has clearly stated that the polypropylene mid-urethral sling is safe and effective in the treatment of SUI."

Do you agree with that statement?

MR. LUNDQUIST: Form.

THE WITNESS: I think you need to look at what is said in that paragraph. That's what I would agree with.

BY MR. HUTCHINSON:

Q But I'm asking you, do you agree with that statement?

A No, I think you need to look at, the FDA continues to evaluate it, its use for the treatment, and will report later, and the FDA says that they have data

up to one year, for multi-incision. This isn't the TVT Secur.

Q Do you disagree that the FDA has stated that polypropylene MUS is safe and effective in the treatment of SUI?

MR. LUNDQUIST: Form.

BY MR. HUTCHINSON:

Q That's something you disagree with?

MR. LUNDQUIST: Form.

THE WITNESS: I agree with what's in the paragraph. I don't agree with that statement. The FDA's continuing to get data about it. So the paragraph is correct, but the statement is, I think, overreaching.

BY MR. HUTCHINSON:

Q Um --

A And if you look at above, in number 1, they said that even for surgical mesh, there's no data past 17 years, in terms of safety. So it's not totally proven, and that's what's going on here. FDA is asking for data.

MR. HUTCHINSON: Move to strike as nonresponsive.

Q Dr. Parisian, let's change gears for a minute. Have you ever participated in a urogynecological

clinical trial?

A No, sir. I haven't participated in one.

Q Have you ever participated in any clinical trial for any medical product?

A You mean me being a subject? No, I've been --

MR. LUNDQUIST: No, I don't think that's what he's saying.

She suggesting she's actually a participant that, like -- just clarifying the question, here.

BY MR. HUTCHINSON:

Q No?

A No, I've not been in. I did some clinical trials back when I was in my hospital days as an ER doctor, I remember having to go to IRBs and stuff. I don't remember what they were, but they were device-type drugs.

Q My question to you is: Have you ever participated in any clinical trial as a participant for a medical device?

A Well, see, I've never been a subject or an investigator in a clinical trial that I'm aware of. I've reviewed them for the FDA and approved them, monitored them, evaluated them, but not been the principal investigator. I think that's what you want to

know.

Q Have you ever participated as a subject in a clinical trial for any type of gynecological product?

A No. No, I haven't. As a subject, the patient?

Q Yeah.

A No.

Q Have you ever tested any type of gynecological product in some type of trial?

A No.

Q You wrote a book at one point called, "Twin Cubs of a White Wolf"?

A Yes, sir.

Q And what is that book about?

A It's a romance novel that I never sold. I used the name McLean Thomas and --

Q Okay, why didn't you use your real name when you published it?

A Because I just felt like -- I registered my name. That's why everybody, all the defense firms know the name. So I haven't hidden the name, but I just didn't use it at the time, and I wrote -- and it's never been sold or distributed. Somehow, defense firms have found it, I guess, at the Library of Congress and some

defense blogs have put it online, with -- which I think is illegal, but I've never sold it. And it has nothing to do with the FDA.

Q Have you ever -- what is the book about, then?

A The book is about a mother that lies, that's the white wolf, and two people that think that she's their mother and she's not.

Q Is it about an incestuous sexual relationship?

MR. LUNDQUIST: Form.

THE WITNESS: No, they're not incestuous. That issue is that they're not related at all, and the mother is allowing them to think they were. So that's where the mother's lying. And I didn't sell it. A lot of judges would love it, but I haven't sold it.

MR. HUTCHINSON: Let me take a quick break.

(Deposition in recess from 3:29 p.m. to 3:43 p.m.)

BY MR. HUTCHINSON:

Q Dr. Parisian, we're back on the record, having taken a break. Do you intend to offer any other opinions in this case other than the ones we've already discussed?

MR. LUNDQUIST: Object to form.

THE WITNESS: No. Could I clarify something about my book?

BY MR. HUTCHINSON:
Q Sure.
A That I said judges would like it, I don't mean the judges would like it. I mean that they're curious as to why a book about -- not about the FDA, that was never sold, is always brought up. So I don't know if they'd like it or not. I wanted to correct that answer.
Q Okay, fine. Is that the only romance novel you've ever written?
A Well, it's the only one ever published. The other one's up in my closet. I'm not going to do that again.
Q Do you recommend doing any -- I mean, I'm sorry, strike that.
Do you plan on doing any work on -- in this case in the future?
A I haven't been asked to.
Q Is there any additional work that you believe that you should do, having now been deposed?
A No.
Q Have you ever been sued?
A No.
Q Have you ever filed bankruptcy?
A No.

Q Has the Court ever determined that you cannot give an expert opinion?
A One court has, and that would be the Trasylol decision in terms of Judge Middlebrooks, and then there was a judge in Arizona here who had a pain pump case who did not think a FDA expert was necessary, and then there was a case for Aredia Zometa, where the judge -- I think Hogan was the name of the case, or the judge, and he determined that neither FDA expert could participate because of the way that the filing was.
Q Has a court ever excluded you as an expert? Is that what you're talking about?
A Yes, sir, those are the ones.
MR. LUNDQUIST: Form.
BY MR. HUTCHINSON:
Q That would be how many cases?
MR. LUNDQUIST: Form.
THE WITNESS: That I know of is Trasylol -- yeah, four.
BY MR. HUTCHINSON:
Q Four. Have you ever been held in contempt of court?
A No.
Q Have you ever been charged or convicted of a crime?
A No.
Q Have you understood all of my questions?
A I've tried to, and I've tried to ask for clarification.
Q Is there anything about the testimony you've given that you'd like to change?
A No.
Q Your middle initial is D, as in David?
A Yes, it's Dorgan.
Q And your husband's name is James W., is that correct?
A Yes, sir.
Q You used to live in West Virginia?
A I used to live in the western part of Virginia, in Fort Royal.
MR. HUTCHINSON: All right, thank you. No further questions.
THE WITNESS: Yes, sir.
MS. FREEMAN: I don't have any questions.
MR. LUNDQUIST: I'm going to have a few, Cynthia.
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EXAMINATION BY MR. LUNDQUIST
BY MR. LUNDQUIST:
Q Good afternoon, Doctor.
A Good afternoon.
Q Certainly we've talked about a lot of your opinions today, but as the designation set forth as Exhibit --
MR. HUTCHINSON: Four.
MR. LUNDQUIST: Thank you.
Q -- 4 reflects, you're intending to give opinions consistent with, obviously, your testimony today in Exhibit number 4, is that fair?
A Pardon?
Q You're intending to give opinions at trial consistent with your testimony today and with respect to Exhibit 4, which would be the designation of experts?
A Yes.
MR. HUTCHINSON: Objection, leading.
THE WITNESS: Yes, sir.
BY MR. LUNDQUIST:
Q All right. I want to talk about, since we haven't really discussed, to some extent, the bases for some of your opinions, Doctor.
As I understood your testimony, is it possible

that there could be an instance where the -- where a polypropylene sling may be appropriate for implantation if the physician has adequate information to do a risk/benefit analysis?

A Yes.

Q Based on your review of documents from Ethicon and the deposition testimony you reviewed and all the various things you reviewed in preparing for your deposition today, do physicians who utilize the TVT Secur have adequate information to conduct a risk/benefit analysis?

MR. HUTCHINSON: Object to form.

THE WITNESS: Based on the information I've reviewed? No.

BY MR. LUNDQUIST:

Q And you actually went through today and discussed some of the data that you have access to that the average urogynecologist or OB-GYN would not have, fair?

A That's correct.

Q And certainly based on your review of Dr. Walss' deposition, you can appreciate that there was a lot of information that we've discussed today that he did not have access to.

MR. HUTCHINSON: Leading.

BY MR. LUNDQUIST:

Q Correct?

A Yes.

Q And you had to sign a confidentiality order to be able to review these documents?

A Yes, sir.

Q You also reviewed deposition testimony from Ethicon employees, correct?

A Yes, sir.

Q And is that deposition testimony something that the average urogynecologist or OB-GYN who implants Ethicon products is going to have at hand?

A No.

Q Is your opinion that a manufacturer could be obligated to do pre-market clinical trials under industry guidelines even if the FDA doesn't require a 510(k) process?

A Yes, as part of design development under 21 C.F.R. 20.

Q What is the basis for that opinion besides a requirement under 21 C.F.R. Part 20?

A Well, and also to ensure that they sell a safe and effective product and make sure that it actually

performs as intended, in terms of the risk versus benefit. So clinical trials are required for certain devices before they get cleared.

Q Part of that would be to establish a -- would you agree that part of that would be to establish a favorable risk/benefit ratio?

A To help develop the IFU, yes, and to also give the label information. Some manufacturers do clinical trials beforehand to get -- so they have it for marketing; they can make claims in terms of benefits.

Q And in terms of your methodology in that opinion, do industry guidelines and standards inform your methodology with respect to that opinion?

A Yes.

Q And that would include the GHTF standards that you cited in your reliance list?

A Yes, as well other -- other industry standards, such as biocompatibility standards, testing standards. There's all kinds of ISO standards, and AAMI standards. So international, United States, industry standards.

Q That would include your work consulting with industry?

A Yes, and it began in my work with the FDA,

I got involved in standards organizations, looking at standards for the FDA, and then after I left FDA, I was a reviewer of voluntary standards for various industry groups.

Q Can clinical trials of similar products be instructive in evaluating the safety and efficacy profile of a device?

A Yes.

Q And so would it be fair to say that while it may be instructive, it would not be appropriate to solely rely on that?

MR. HUTCHINSON: Objection, leading.

THE WITNESS: Yeah, if there's significant differences, you have to take into consideration what are the differences and how will they potentially change the safety and effectiveness.

BY MR. LUNDQUIST:

Q And what types of differences are you talking about, particularly in the context of the TVT Secur?

A Well, in terms of the change in the mesh that we went through at 8 centimeter; that you're using Ethisorb as a fixation component, or the Christmas tree formation, which is new -- we haven't talked about that -- to stabilize the mesh; that you're using a new

inserter that is sharp as opposed to the other inserter; that you're saying that this device can be used for either a retropubic or a hammock configuration, which was new, that one mesh would be sold for both. I went into some of that.

Q Okay. So in other words, when you are talking in your designation -- you testified somewhat today, but when you're trying to determine whether a product is safe and effective, separate and apart from looking at clinical data from similar products, you would also look at, if they were done, pre-market clinical studies on a particular product.

A Right, right. You could also begin looking at the literature, the medical literature, for other products that are similar to what you're considering. So it's not just your own products. You can look at what other -- the history of other products.

Q And this is the methodology that you employed as a medical officer within the FDA as well, fair?

MR. HUTCHINSON: Objection, leading.

THE WITNESS: Well, yes, and this is the methodology that manufacturers employ and the FDA anticipates they will employ when you have them come for -- industry come in for meetings. You ask them,

"What did you look at?" if they have a meeting, and they'll usually talk about animal data, studies that they've done, other similar studies, industry standards. FDA allows companies to cite certain industry standards. So yeah, that's the typical process around designing a medical device.

BY MR. LUNDQUIST:

Q Okay, you told me just a minute ago that industry standards and guidelines informed your methodology and your opinion on whether or not pre-market clinical trials are necessary for the TVT Secur.

A Well, it's not just that. That would contribute, but also my experience as a physician, and my knowledge and training as to what the potential risks are to human beings. So those would also feed into it.

Q After leaving the FDA -- well, let me ask you this: While you were at the FDA, were you on these types of industry standards committees?

A Yes, I was assigned, particularly in the Office of Health Affairs, to be involved in standards committees.

Q And then after leaving the FDA, were you ever on an industry standards committee?

A Yes, it continued on.

Q So we talked about the various industry standards separate and apart from the FDA regulations and guidance documents that you've utilized, right?

A Yes.

Q Okay. Can clinical -- strike that. Can industry standards and guidelines require pre-market clinical trials, even though they don't specifically call out polypropylene transvaginal mesh?

A Yes, and also the medical literature, the history of the product, devices, all of these things have to be taken into consideration, particularly if you're changing the device.

Q Why?

A Because you have to ensure that it's going to work in terms of the patient, it's going to do what it's supposed to do, and there are many new features with this product that needed to be addressed.

Q So in addition to the testimony you've given as to why you believe Ethicon should have conducted pre-market clinical trials, do you have.... Well, strike that. What is HAS?

A HAS is a French organization that did a review of the types of studies that needed -- information that

needed to be for pelvic procedures, and I think the name is the French National Authority for Health, HAS.

Q And that was listed in your reliance list, was it not?

A Yes.

Q That's something you relied on in rendering your opinions in this matter?

A Yes. And you asked about standards also supporting pre-clinical. It was also the company's documents and their own internal discussion that they needed clinical data before they had it launched.

MR. HUTCHINSON: Move to strike as nonresponsive.

BY MR. LUNDQUIST:

Q So we're clear, the HAS is not the FDA equivalent in France; is that fair?

MR. HUTCHINSON: Objection, leading.

THE WITNESS: I don't believe it is. Now, let me look. I'm not sure. It could be. I don't want to say it isn't. I'm not sure what their FDA is called. This is their national authority for health. So it may be their FDA equivalent. I know they have a different name, but that may somehow be connected to them.

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BY MR. LUNDQUIST:
Q Just so we're clear -- I think you have testified to this -- when you were formulating your opinions on whether or not pre-market clinical trials were necessary for the TVT-S, you relied on this HAS study, did you not?
MR. HUTCHINSON: Objection, leading.
THE WITNESS: Yes. There's a HAS study that is similar to the NICE study, in that they're talking about funding. Their focus is on funding of effective procedures. So I believe that's where HAS comes in.
BY MR. LUNDQUIST:
Q Okay, well, back up. What is NICE?
A NICE is a group in the United Kingdom that looks at the efficacy of products that are offered for treatment, and they get into whether they're going to fund it in terms of socialized medicine. So they're actually technology-assessment types of organizations.
Q Oh, there it is, and that's also listed on your reliance list as having reviewed this document to substantiate these opinions you've given today?
A Right.
Q The National -- the National Institute for Health Care Excellence?

A Yes. It's a technology assessment.
Q The GHTF guidelines that you reviewed, are those guidelines still utilized in industry today?
A Yes, because products are now becoming more global, and so the FDA and different regulatory agencies are trying to harmonize requirements and the procedures and processes that manufacturers do, to try to have some overlap, so that there's a consistency with the types of requirements for marketing product.
Q Do you have personal knowledge as to whether the industry -- strike that. Do you have personal knowledge as to whether industry had any input into the formulation of those guidelines?
A Industry typically does, but it's also through the regulatory bodies that are on those different panels. So industry does, because they also sit on those panels, but the regulatory bodies do, too.
Q In your consulting work with industry, do you utilize the GHTF -- did you utilize the GHTF guidelines?
A Yes, yes, especially for post-market surveillance for devices.
Q And so we're clear, the GHTF guidelines are not federal regulations, are they?
MR. HUTCHINSON: Objection, leading.

THE WITNESS: Not unless FDA adopts them specifically, and then they often oftentimes will issue something that they have adopted.
BY MR. LUNDQUIST:
Q And the same would be true for the ISO standards that you talked about earlier; those are not federal regulations?
A Those are not federal regulations. FDA will allow certain ones to be used by manufacturers. FDA kind of picks and chooses which consensus documents they're going to accept in the standards.
Q You were asked some questions by counsel about your opinions on the types of pre-market trials and pre-market data that needed to be done by Ethicon prior to marketing its products. Do you recall that?
A Yes.
Q Your opinions on the types of trials and the types of testing and the types of data that Ethicon should have done prior to commercialization are not based solely on what you want; is that fair?
A Well, they're not subjective opinions. They're based on the company's documents and also some of the issues of safety and effectiveness. The HAS document actually talks about the type of information

that should be obtained. So they're from various sources.
Q So did you -- so essentially, did you rely on industry guidelines to inform you what would be an appropriate pre-market clinical trial?
A That would be that, and also company documents in terms of what they've done, and also my own training and experience looking at similar types of issues for the FDA, for clinical trials.
Q Now, in order to -- in terms of the labeling of the IFU in regard to the TVT Secur, in order to use the device safely, do you need to know about the severity of the complications?
A The labeling -- yes, the labeling is supposed to indicate the severity and the frequency, and it's not jut the IFU, it's also the marketing. The marketing has to be consistent with the potential risks and benefits. You can't overstate benefits and not give the risk information.
Q And so we're clear, nowhere in the IFU that you looked at today does it talk about severity, permanence or frequency of the adverse events, does it?
A Right, and that's the information you originally get cleared, but you get that information as

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the product is being used, and the label is a living thing. It's supposed to be updated with your post-market information for physicians. They call it the Total Product Life Cycle, TPLC, that the manufacturer updates their labels.

Q And that type of information is information the investigator would need to know to be able to appropriately -- strike that.

Whose responsibility is it to ensure that the information is -- adequate information is contained in the instructions for use?

MR. HUTCHINSON: Objection, form.

THE WITNESS: The manufacturer.

BY MR. LUNDQUIST:

Q You can answer.

A The manufacturer, according to the Act and implementing regulations.

Q And who writes the IFU?

A The manufacturer, and they could update it at any time.

Q And separate and apart from FDA regulations that you talked about, if a complication is potentially going to be permanent, and that is a foreseeable risk by the manufacturer, should it be included, based on

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industry guidelines, in the instructions for use?

A Yes. In terms of adequate warnings, yes.

Q And the same would be true with respect to severity?

MR. HUTCHINSON: Objection, leading.

THE WITNESS: Yes.

BY MR. LUNDQUIST:

Q Frequency?

MR. HUTCHINSON: Leading.

THE WITNESS: Right. Well, an adequate label is supposed to have that information.

MR. HUTCHINSON: Move to strike as nonresponsive.

BY MR. LUNDQUIST:

Q And with respect to your opinions on labeling, have you ever referred to and used and relied on industry guidelines, separate and apart from the FDA regulations?

A Yes. That's part of my training. I'm trained in those.

Q The same would be true for your opinions on post-market surveillance?

MR. HUTCHINSON: Leading.

THE WITNESS: Yes.

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BY MR. LUNDQUIST:

Q What is the basis of your opinions on post-market surveillance that you've given today?

A It's particularly having worked in OHA in the post-market surveillance group -- I mean, the post-marketing issues, and having dealt with MDRs and follow-up and looking at adequacy of warnings and labeling. So that was what I was involved in in the first couple years, and then I continued on, since I was first trained in it.

Q Does the length of.... One of the categories you were designated on is the literature reflecting the problems that surgeons were experiencing with the TVT Secur.

A That should be added to the list.

MR. HUTCHINSON: Objection, form.

BY MR. LUNDQUIST:

Q And -- well, let's just ask. What is the basis for your opinion that the literature reflected that surgeons were experiencing problems with the TVT Secur?

A Well, the published literature was, and then the KOLs, people discussing it with the -- it's based on the company documents and information -- where are you?

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Q It's on page 13, middle of 13.

A Yes, it would be based on the company documents and also the -- from the physicians, and then you look at the Cochran report. The Cochran report actually did a randomized controlled study and review and set out the potential risks, and that wasn't in the labels. So they actually looked at all the literature for us and said that there were -- needed to be warnings.

Q Okay, and we're talking about the warnings, the -- obviously, you believe the Instructions for Use was inadequate related to the TVT Secur.

MR. HUTCHINSON: Objection, leading.

THE WITNESS: It was inadequate because it wasn't being updated. It first got cleared, and then as more information was coming, particularly in 2007, 2008, that information wasn't being added. Even before it was launched, it wasn't updated, in terms of the first amendment for the design validation. The doctors said, update the IFU. Internally, the company's doctors are saying, update the IFU, the Instructions For Use, and they weren't updating the information.

So internally, the company was saying it. I think Dan Smith was the one primarily not wanting to

update the information. There was discussion about needing a "cookbook" to teach the doctors how to put the devices in, and that wasn't being done in terms of the labels, and it was never updated.

MR. HUTCHINSON: Move to strike as nonresponsive.

BY MR. LUNDQUIST:

Q And so the inadequacy of the warning --

MR. HUTCHINSON: I'm sorry, did you get my objection?

THE REPORTER: Yes, I did.

BY MR. LUNDQUIST:

Q The inadequacy of the warnings that you've talked about today, that's not just based on the FDCA; that's based on these other guidelines and standards that we've talked about. Is that fair?

MR. HUTCHINSON: Object to form.

THE WITNESS: Well, it's based on other guidelines and standards. It's also based on my experience as a physician and training as a physician being able to understand what's being reported, in that a physician needs to know that information. And it's further supported by Dr. Miklos.

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BY MR. LUNDQUIST:

Q So with respect to your opinions on labeling, have you referred to and used and relied on industry guidelines, separate and apart from FDA regulations?

A Yes.

Q Okay, and the same --

A And adequate labels and discussion of adequate labels, yes.

Q Sure. Same would be true for your opinions on post-market surveillance?

MR. HUTCHINSON: Objection to form.

THE WITNESS: Correct, and that would also come under corrective and preventive action, when you're having issues, but that's FDA, again.

MR. HUTCHINSON: Move to strike as nonresponsive.

BY MR. LUNDQUIST:

Q Talking about the literature, would the length of a study play a role in whether or not you can determine if a particular patient might have future complications?

A Yes, totally, and you have to take that into consideration, is it six weeks versus twelve weeks, or if it's a follow-up. So you have to be able to review

the medical literature. That's where my training and experience in looking at literature comes from.

Q Would pre-market clinical trials, if designed appropriately, give us information on frequency of complications?

A Yes.

Q How do you know that?

A Well, especially because the reports were actually coming at 12 weeks in terms of failures. So even a short-term trial, less than a year, would come up with this information.

Q And would a pre-market clinical trial, if designed appropriately, also give you information on -- strike that.

But would a pre-market clinical trial, if designed appropriately, give us information on the severity of complications?

A Yes.

Q Obviously, that would be before the product was placed on the market.

A Correct.

MR. HUTCHINSON: Objection, form.

THE WITNESS: And then the company proposed to have a registry to give that information, which they

didn't follow through. That was -- the TVT world was listening, but they didn't follow up with it.

MR. HUTCHINSON: Objection, nonresponsive.

BY MR. LUNDQUIST:

Q Is it possible for an industry guideline to take into account every single medical device and then give you a list of exactly what type of -- or kind of trial needs to be done?

MR. HUTCHINSON: Form.

THE WITNESS: No, no. The company is responsible for their own design. Because there's so many types of devices, so many types of issues, the manufacturer is the expert. The manufacturer has to take into consideration the potential risks. They look at the literature, other similar trials, and they design what they need to look at in terms of their product.

But no, I don't know of any government agency or industry standard that is specific for all medical device manufacturers, because of the variety of devices.

MR. LUNDQUIST: Doctor, I think that's all the questions I have. I'll pass the witness.

MR. HUTCHINSON: Assuming, Cynthia, you don't have any follow-up questions, is that correct? Cynthia Freeman?

MS. FREEMAN: Yeah, that's right, I don't have any.

MR. HUTCHINSON: Okay, I've got just a couple.

FURTHER EXAMINATION BY MR. HUTCHINSON

BY MR. HUTCHINSON:

Q Dr. Parisian, according to your reliance list, you relied on the GHTF guidelines, correct?

A Yes, sir.

Q And these are standards that relate to safety?

A Yes, sir.

Q These are standards that apply to Ethicon's products?

A Worldwide products, yes, sir.

Q Including TVT Secur?

A All of them.

Q And these standards are mandatory for Ethicon to follow, correct?

A No. They're mandatory for them to consider and then create their own procedures that would be adherent to them wherever they want to market their product.

Q I asked you earlier about your participation as a subject in a clinical trial. Have you ever designed a clinical trial for any type of gynecological

product?

A Not for a gynecological product. I was required at FDA to design -- oh, wait a second. That's basically right, in terms of that, because breast cancer is not really gynecological. You were talking about pelvis.

Q And you have never helped with a clinical trial in any type of urology, correct?

A That's correct, yes.

MR. HUTCHINSON: I don't have any further questions. Thank you for your time.

THE WITNESS: Can I clarify one other thing? You asked me about bankruptcy and suits. My husband has filed bankruptcy, and there's been some suits against him, lawsuits against him.

MR. LUNDQUIST: I don't think he asked you that.

THE WITNESS: No, but I wanted to clarify for him that I wasn't saying no, but they were my husband's, so I don't know anything about those.

BY MR. HUTCHINSON:

Q Well, when did your husband file bankruptcy?

MR. LUNDQUIST: Form.

MR. HUTCHINSON: What's the matter with the

form, counsel?

MR. LUNDQUIST: It's completely irrelevant.

THE WITNESS: Well, no, he filed bankruptcy years ago. I don't know, I think like 10 -- 10, 11 years ago. I didn't. I don't know anything about it, but I don't know -- I'm not -- the specifics of it.

BY MR. HUTCHINSON:

Q How much money -- were you and your husband married back in 2000?

A Yes, sir.

Q How much, back in 2000, how much money were you making then, doing litigation services?

A About -- I don't know, 400,000, 500,000.

MR. HUTCHINSON: All right, no further questions. Thanks.

Before everybody goes -- and why don't we stay on the record -- let the record reflect that we have 16 exhibits, and what we'll do is, plaintiff's counsel and I will try to make sure we have all of them together, and then we'll get back the record.

(Discussion off the record.)

MR. HUTCHINSON: All right, so we're back on the record. Let the record reflect that we have 16 exhibits attached to this deposition, and that

plaintiff's counsel, and I as counsel for Ethicon, have both looked at the exhibits and believe that they are complete. Is that right?

MR. LUNDQUIST: That's fair.

MR. HUTCHINSON: All right, thanks. That's all we have.

THE REPORTER: Okay.

MR. HUTCHINSON: Wait, back on the record.

And let's also make a record that the two big black binders that have tabs in one of them, 1 through 69, and 1 through 23 in another one, are going to be given to the court reporter, let him have possession of these for him to make sure that complete and color copies are made, and that he will be responsible for submitting them directly to the witness. Okay? Thank you.

(Deposition concluded at 4:20 p.m.)

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CERTIFICATE

I, LEO T. MANKIEWICZ, CR, a Certified Reporter in the State of Arizona, do hereby certify that an oath was duly administered to the witness Suzanne Parisian, M.D., pursuant to A.R.S. §41-324(B) and that the foregoing pages constitute a full, true, and accurate transcript of the proceedings had in the foregoing matter, all done to the best of my skill and ability.

The witness herein, Suzanne Parisian, M.D., has requested signature.

SIGNED and dated this 20th day of February, 2015.

____

LEO T. MANKIEWICZ, CR, RMR, CRR
Certified Reporter
Certificate No. 50778

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Please read your deposition over carefully and make any necessary corrections. You should state the reason in the appropriate space on the errata sheet for any corrections that are made.

After doing so, please sign the errata sheet and date it. It will be attached to your deposition.

It is imperative that you return the original errata sheet to the deposing attorney within thirty (30) days of receipt of the deposition transcript by you. If you fail to do so, the deposition transcript may be deemed to be accurate and may be used in court.

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ACKNOWLEDGMENT OF DEPONENT

I,_____________________, do hereby certify that I have read the foregoing pages, and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

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SUZANNE PARISIAN, M.D. DATE

Subscribed and sworn to before me this _____ day of _______________, 20____.

My commission expires:_______________

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Notary Public

LAWYER'S NOTES

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